Interventions for promoting the initiation of breastfeeding

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[Intervention Review]

Interventions for promoting the initiation of breastfeeding

Olukunmi O Balogun[1], Elizabeth J O'Sullivan[2], Alison McFadden[3], Erika Ota[4], Anna Gavine[5], Christine D Garner[6], Mary J Renfrew [3], Stephen MacGillivray[5]

[1]Department of Health Policy, National Center for Child Health and Development, Tokyo, Japan. [2]School of Medicine, University College Dublin, Dublin, Ireland. [3]Mother and Infant Research Unit, School of Nursing and Health Sciences, University of Dundee, Dundee, UK. [4]Global Health Nursing, St. Luke's International University, Graduate School of Nursing Sciences, Tokyo, Japan. [5]evidence Synthesis Training and Research Group (eSTAR), University of Dundee, Dundee, UK. [6]Division of Nutritional Sciences, Cornell University, Ithaca, NY, USA

Contact address: Olukunmi O Balogun, Department of Health Policy, National Center for Child Health and Development, 2-10-1 Okura, Setagaya, Tokyo, Tokyo, 157-8535, Japan. omobolanle_balogun@yahoo.com, balogun-o@ncchd.go.jp.

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ABSTRACT

Background

Despite the widely documented risks of not breastfeeding, initiation rates remain relatively low in many high-income countries, particularly among women in lower-income groups. In low- and middle-income countries, many women do not follow World Health Organization (WHO) recommendations to initiate breastfeeding within the first hour after birth. This is an update of a Cochrane Review, first published in 2005.

Objectives

To identify and describe health promotion activities intended to increase the initiation rate of breastfeeding.

To evaluate the effectiveness of different types of breastfeeding promotion activities, in terms of changing the number of women who initiate breastfeeding.

To evaluate the effectiveness of different types of breastfeeding promotion activities, in terms of changing the number of women who initiate breastfeeding early (within one hour after birth).

Search methods

We searched Cochrane Pregnancy and Childbirth's Trials Register (29 February 2016) and scanned reference lists of all articles obtained.

Selection criteria

Randomised controlled trials (RCTs), with or without blinding, of any breastfeeding promotion intervention in any population group, except women and infants with a specific health problem.

Data collection and analysis

Two review authors independently assessed trial reports for inclusion, extracted data and assessed trial quality. Discrepancies were resolved through discussion and a third review author was involved when necessary. We contacted investigators to obtain missing information.

Main results

Twenty-eight trials involving 107,362 women in seven countries are included in this updated review. Five studies involving 3,124 women did not contribute outcome data and we excluded them from the analyses. The methodological quality of the included trials was mixed, with significant numbers of studies at high or unclear risk of bias due to: inadequate allocation concealment (N = 20); lack of blinding of outcome assessment (N = 20); incomplete outcome data (N = 19); selective reporting (N = 22) and bias from other potential sources (N = 17).

Healthcare professional-led breastfeeding education and support versus standard care

The studies pooled here compare professional health workers delivering breastfeeding education and support during the prenatal and postpartum periods with standard care. Interventions included promotion campaigns and counselling, and all took place in a formal setting. There was evidence from five trials involving 564 women for improved rates of**breastfeeding initiation** among women who received healthcare professional-led breastfeeding education and support (average risk ratio (RR) 1.43, 95% confidence interval (CI) 1.07 to 1.92; $Tau^2 = 0.07$, $I^2 = 62\%$, low-quality evidence) compared to those women who received standard care. We downgraded evidence due to design limitations and heterogeneity. The outcome of **early initiation of breastfeeding** was not reported in the studies under this comparison.

Non-healthcare professional-led breastfeeding education and support versus standard care

There was evidence from eight trials of 5712 women for improved rates of **breastfeeding initiation** among women who received interventions from non-healthcare professional counsellors and support groups (average RR 1.22, 95% CI 1.06 to 1.40; $Tau^2 = 0.02$, $I^2 = 86\%$, low-quality evidence) compared to women who received standard care. In three trials of 76,373 women, there was no clear difference between groups in terms of the number of women practicing **early initiation of breastfeeding** (average RR 1.70, 95% CI 0.98 to 2.95; $Tau^2 = 0.18$, $I^2 = 78\%$, very low-quality evidence). We downgraded the evidence for a combination of design limitations, heterogeneity and imprecision (wide confidence intervals crossing the line of no effect).

Other comparisons

Other comparisons in this review also looked at the **rates of initiation of breastfeeding** and there were no clear differences between groups for the following comparisons of combined healthcare professional-led education with peer support or community educator versus standard care (2 studies, 1371 women) or attention control (1 study, 237 women), breastfeeding education using multimedia (a self-help manual or a video) versus routine care (2 studies, 497 women); early mother-infant contact versus standard care (2 studies, 309 women); and community-based breastfeeding groups versus no breastfeeding groups (1 study, 18,603 women). None of these comparisons reported data on **early initiation of breastfeeding**.

Authors' conclusions

This review found low-quality evidence that healthcare professional-led breastfeeding education and non-healthcare professional-led counselling and peer support interventions can result in some improvements in the number of women beginning to breastfeed. The majority of the trials were conducted in the USA, among women on low incomes and who varied in ethnicity and feeding intention, thus limiting the generalisability of these results to other settings.

Future studies would ideally be conducted in a range of low- and high-income settings, with data on breastfeeding rates over various timeframes, and explore the effectiveness of interventions that are initiated prior to conception or during pregnancy. These might include well-described interventions, including health education, early and continuing mother-infant contact, and initiatives to help mothers overcome societal barriers to breastfeeding, all with clearly defined outcome measures.

PLAIN LANGUAGE SUMMARY

Interventions for encouraging women to start breastfeeding

What is the issue?

International rates of breastfeeding initiation are extremely variable both between and within countries. Low- and middle-income countries generally have high rates of women starting breastfeeding, and the challenge is for breastfeeding to begin within one hour of birth. High-income countries have a much greater variation in the number of women who start breastfeeding, with more highly educated and more well-off women likely to start.

The World Health Organization recommends that breastfeeding should start within the first hour after giving birth, that all infants should be exclusively breastfed from birth to six months of age, and that breastfeeding should continue until 2 years or beyond. We know that breastfeeding is good for the health of women and babies. Babies who are not fully breastfed for the first three to four months of life are more likely to suffer from infections of the stomach and intestines, air passages and lungs, or develop ear infections. Babies who are not breastfed are more likely to be overweight or have diabetes later in life, and mothers who do not breastfeed have increased risks of breast and ovarian cancer. Other practical benefits of breastfeeding include saving money on buying breast milk substitutes and, for society, on treating illness. Yet many women feed their babies with infant formula.

Why is this important?

We want to have a better understanding of what works to promote breastfeeding, for women, their families, the health system and society. Women face many barriers to breastfeeding, including lack of public spaces where women can breastfeed without feeling embarrassment; lack of flexible working days for breastfeeding women at work; widespread advertising of breast milk substitutes; and public policy that ignores the needs of breastfeeding women. New ways to promote breastfeeding are needed.

What evidence did we find?

We searched for evidence on 29 February 2016. This updated review now includes 28 randomised controlled studies involving 107,362 women. Twenty studies involving 27,865 women looked at interventions to increase the number of women who started breastfeeding, in three high-income countries (Australia, 1 study; UK, 4 studies; and USA, 14 studies) and one lower middle-income country (Nicaragua, 1 study). Three studies investigated the effect of an intervention to increase the number of women who started breastfeeding early, within one hour after birth. These involved 76,373 women from Malawi, Nigeria and Ghana. The study from Malawi was large, with 55,931 participants.

Health education delivered by doctors and nurses and counselling and peer support by trained volunteers improved the number of women who began breastfeeding their babies. Five studies involving 564 women reported that women who received breastfeeding education and support from doctors or nurses were more likely to start breastfeeding compared to women who received standard care. Four of these studies were conducted in low-income or amongst minority ethnic women in the USA, where baseline breastfeeding rates are typically low. Eight studies involving 5712 women showed improved rates of starting breastfeeding with trained volunteer-delivered interventions and support groups compared to the women who received standard care.

Breastfeeding education provided by trained volunteers could also improve the rates of early initiation of breastfeeding, within one hour of giving birth, in low-income countries.

We assessed all the evidence in this review to be low-quality because of limitations in study design and variations in the interventions, to whom, when, where, and how an intervention was delivered. Standard care also differed and could include some breastfeeding support, for example, in the UK.

We found too little evidence to say whether strategies with multimedia, early mother-infant contact, or community-based breastfeeding groups were able to improve breastfeeding initiation.

What does this mean?

Health professionals with training in breastfeeding including midwives, nurses, and doctors, and trained volunteers can deliver education sessions and provide counselling and peer support to increase the number of women who start breastfeeding their babies. High-quality research is needed to understand which interventions are likely to be effective in different population groups. More studies are needed in low- and middle-income countries to find out which strategies will encourage women to start breastfeeding just after giving birth.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

Population: women exposed to interventions intended to promote breastfeeding
Setting: USA, Ireland
Intervention: healthcare professional-led breastfeeding education and support
Comparison: standard care

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with standard care	Risk with health-care professional-led breastfeeding education and support				
Initiation of breastfeeding	Study population		average RR 1.43 (1.07 to 1.92)	564 (5 RCTs)	⊕⊕◯◯ LOW [1,2]	It is not possible to blind this type of intervention and so we have not downgraded for lack of blinding
	418 per 1000	598 per 1000 (448 to 808)				
Early initiation of breastfeeding	No trial included in this comparison measured the outcome of early initiation of breastfeeding					

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).
CI: confidence interval; **RCT**: randomised controlled trial; **RR:** risk ratio.

GRADE Working Group grades of evidence
High quality: We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[1] Most studies were unclear for allocation concealment and some studies were of high risk for attrition bias. Downgraded for risk of bias (-1).
[2] High heterogeneity (I^2 > 60%) (-1).

BACKGROUND

Description of the condition

There is extensive, good-quality evidence for short-term and long-term health risks of formula-feeding. The World Health Organization (WHO) recommends initiation of breastfeeding within the first hour after birth, exclusive breastfeeding for the first six months, with continued breastfeeding along with appropriate complementary foods up to two years of age or beyond (WHO 2003). Babies who are not breastfed are more likely to suffer infectious diseases such as gastroenteritis, respiratory disease, and otitis media (middle-ear infections) leading to increased hospitalisation, morbidity, and mortality (Bowatte 2015; Horta 2013; Sankar 2015). Children who have not been breastfed have increased rates of childhood diabetes and obesity (Horta 2015a), and increased dental disease (Peres 2015; Tham 2015). In addition, there is evidence of an adverse impact of not being breastfed on IQ, and educational and behavioural outcomes for the child (Heikkilä 2011; Heikkilä 2014; Horta 2015b; Quigley 2012). For women, good-quality evidence shows associations between *not* breastfeeding and increased risks of breast and ovarian cancer, and diabetes (Chowdhury 2015). For preterm babies, a diet of exclusive breast milk reduces the incidence of necrotising enterocolitis - a disease of the gastrointestinal tract of premature infants that results in inflammation and bacterial invasion of the bowel wall (Hermann 2014; Ip 2007).

Attempts have been made to quantify public cost benefits of breastfeeding. The global cost burden of not breastfeeding was estimated by Rollins 2016 to be USD 302 billion annually. In the UK, Renfrew 2012a estimated that a modest increase in breastfeeding rates could save over GBP 17 million per annum by avoiding the costs of treating four acute diseases in infants (gastrointestinal infection, lower respiratory tract infection, otitis media, and necrotising enterocolitis).

International rates of initiation of breastfeeding are extremely variable between and within countries. As data are gathered using different methods in different settings, reported rates should be treated with caution. From countries where data are available, low- and middle-income countries generally have high rates of breastfeeding initiation of over 90% (Victora 2016b). However there is often a delay in initiating breastfeeding beyond the first hour after birth, which increases neonatal mortality (NEOVITA Study Group 2016). The world average for early initiation of breastfeeding is 44% (UNICEF 2014), however there is wide variation, with some countries such as India and Pakistan reporting rates of 23.3% and 18.4% respectively (Victora 2016b). In high-income countries, there is wide variation of breastfeeding initiation. Many countries report rates of over 90% such as Australia, Chile, the Nordic countries, Italy, Japan, Russia, and Saudi Arabia (Victora 2016b); however, lower rates are reported from the UK (81%), the USA (79%), France (63%), and the Republic of Ireland (55%) (Victora 2016b). However, country-level breastfeeding rates conceal geographical and social gradients in breastfeeding initiation. For example, in the UK, breastfeeding initiation rates range from 83% in England to 64% in Northern Ireland (McAndrew 2012). At the same time, there is a stark social-class gradient with the highest incidence of breastfeeding in women aged over 30 years (87%), those who continued education beyond 18 years (91%), and those in managerial and professional occupations (90%) (McAndrew 2012). In the USA, the lowest rates of breastfeeding initiation are among black women (54%) (CDCP 2010).

One of the major factors contributing to low rates of breastfeeding initiation is the influence of the breast milk substitute industry. It has been estimated that the retail value of the industry will reach USD 70.6 billion by 2019 (Rollins 2016). Inadequate implementation and enforcement of The International Code of Marketing of Breast Milk Substitutes (WHO 1981) is one key factor influencing women's decision to breastfeed, and the belief that, in spite of the evidence to the contrary, infant formula has equivalent nutritional value to breast milk (McFadden 2016). It is unclear whether the availability of subsidised infant formula milk through welfare food programmes, such as the UK-based Healthy Start Programme and the USA-based Special Supplemental Nutrition Program for Women, Infants, and Children, is an economic factor which contributes unintentionally to women in low-income groups deciding to formula feed (see for example Jiang 2010).

Description of the intervention

The decision to breastfeed is influenced by multiple complex factors at the individual, family, health system, and societal levels (Dyson 2010). Consequently, there are many approaches to promoting the initiation of breastfeeding which may target pregnant women, their families, wider communities and society, or the health service. Interventions to promote the initiation of breastfeeding are delivered before the first feed, i.e. before or during pregnancy, or immediately after birth.

Interventions targeted to individual women include health education, peer support, practical skills training and early mother-and-baby contact. Health education interventions to promote the initiation of breastfeeding delivered during pregnancy may entail one or more sessions, be delivered to groups or one-to-one, in formal or informal settings, and be delivered by health professionals, maternity support workers, or peer supporters who may be trained or untrained. Breastfeeding health education may be targeted to women alone or it may include family members such as partners and parents (Grassley 2007; Ingram 2004). The content of health education to promote the initiation of breastfeeding may include the health outcomes of breastfeeding compared to formula-feeding, what to expect when breastfeeding, and how to prevent and solve breastfeeding-related problems. It may also include practical skills such as positioning and attachment of the baby at the breast, and the opportunity to talk to a breastfeeding woman and

observe a breastfeed. There is increasing focus on health education approaches to predict and support behaviour change, such as motivational interviewing and the Theory of Planned Behaviour (see for example Copeland 2015; Lawton 2012).

Peer support interventions to promote the initiation of breastfeeding are generally targeted at communities where breastfeeding rates are low, and involve contact between a pregnant woman and a woman from a similar background who has experience of breastfeeding (Phipps 2006). This type of mother-to-mother support has been shown to increase breastfeeding initiation rates (Dyson 2006). Peer supporters undergo varying lengths and styles of training, can be paid or unpaid, and they can be integrated into the healthcare team or separate.

The most effective health service intervention to promote the initiation of breastfeeding is the WHO/United Nations International Children's Emergency Fund (UNICEF) Baby Friendly Hospital Initiative (BFHI), also known in some countries as the Baby Friendly Initiative (BFI). The BFHI/BFI is a multifaceted, structured programme that involves organisational change (Beake 2012). The BFHI/BFI comprises implementation of the Ten Steps to Successful Breastfeeding (WHO/UNICEF 1989), that cover policy, staff training, promotion and support of breastfeeding, limiting use of infant formula, teats and pacifiers, and keeping mothers and babies together (rooming-in) (Pérez-Escamilla 2016). Implementation of BFHI/BFI has increased breastfeeding initiation rates in Israel, Taiwan, UK, and USA (Beake 2012; Pérez-Escamilla 2016).

Mass media campaigns are interventions that are targeted toward wider society, and, when implemented alongside other interventions have had some success at increasing breastfeeding initiation rates (Fairbank 2000).

How the intervention might work

Interventions to promote the initiation of breastfeeding work in different ways that are likely to be context-specific, to vary according to individual needs and circumstances (Rollins 2016), and to vary by each country's economic status and breastfeeding rates. Successful interventions work through addressing the many structural, societal, economic, and individual influences on the decision to breastfeed (Rollins 2016). These include increasing women's motivation to breastfeed, whether that be via providing information about the health outcomes of breastfeeding, providing women with the skills and confidence to commence breastfeeding, or using more structured approaches such as motivational interviewing that seek to 'increase an individual's belief that they can achieve a desired outcome' (Copeland 2015). Interventions that focus on women's families and wider communities attempt to change societal perceptions and norms regarding infant-feeding (Rollins 2016), reducing the impact of these barriers. These types of interventions are particularly important in communities where breastfeeding rates are low and there is an entrenched infant formula-feeding culture. Structured programmes such as BFHI/BFI work through addressing many of the negative influences on women's infant-feeding decisions that derive from health service policy and the knowledge, skills, and attitudes of health personnel (Rollins 2016). Not least of these is protecting women and staff from the influence of marketing and promotion of breast milk substitutes (Piwoz 2015).

Why it is important to do this review

The purpose of this review is to examine interventions which aim to encourage women to breastfeed, to evaluate their effectiveness in terms of changes in the number of women who initiate breastfeeding, and in terms of changing the number of women who initiate breastfeeding early (within one hour after birth). It is important to do this review to inform the design of interventions to promote the initiation of breastfeeding. Increasing rates of initiation of breastfeeding is the first step towards meeting WHO recommendations for breastfeeding and realising the potential of breastfeeding in improving health, reducing the economic burden of ill health, and reducing health inequalities. It is also important to undertake this review to find effective interventions to counter the promotion of breast milk substitutes by the infant formula industry. The amount of money invested by formula manufacturers is many times greater than the amount spent by governments on promoting breastfeeding (Lutter 2013). The published Cochrane Review on support for healthy breastfeeding mothers with healthy term babies found that interventions had more effect on increasing exclusive breastfeeding before four to six weeks and before six months in settings where there were high background rates of breastfeeding initiation compared to areas where there were low or intermediate rates (Renfrew 2012b).

OBJECTIVES

1. To identify and describe health promotion activities intended to increase the initiation rate of breastfeeding.

2. To evaluate the effectiveness of different types of breastfeeding promotion activities, in terms of changing the number of women who initiate breastfeeding.

3. To evaluate the effectiveness of different types of breastfeeding promotion activities, in terms of changing the number of women who initiate breastfeeding early (within one hour after birth).

METHODS

Criteria for considering studies for this review

Types of studies

We included individual randomised controlled trials (RCTs) or cluster-RCTs, with or without blinding. There was no limitation of study by country of origin or language. We excluded quasi-randomised trials and cross-over trials. We also excluded abstracts for which we could not find the full reports.

Types of participants

Women exposed to interventions intended to promote breastfeeding. This includes pregnant women, mothers of newborn infants, and women who may decide to breastfeed in the future. We also included population subgroups of women, such as women from low-income or ethnic groups. Women and infants with a specific health problem, e.g. mothers with HIV/AIDS or infants with cleft palate, or premature babies, are excluded from this review.

Types of interventions

Any intervention aiming to promote the initiation of breastfeeding, which takes place before the first breastfeed. Evaluations of interventions taking place after the first breastfeed or whose primary purpose is to affect the duration or exclusivity of breastfeeding are excluded from this review.

Types of outcome measures

This review includes studies that do and do not contribute outcome data.

Primary outcomes

1. Initiation of breastfeeding.
2. Early initiation of breastfeeding (within one hour after birth).

Secondary outcomes

There were no secondary outcomes included in this review.

Search methods for identification of studies

The following methods section of this review is based on a standard template used by Cochrane Pregnancy and Childbirth.

Electronic searches

We searched Cochrane Pregnancy and Childbirth's Trials Register by contacting their Information Specialist (29 February 2016).
The Register is a database containing over 22,000 reports of controlled trials in the field of pregnancy and childbirth. For full search methods used to populate Pregnancy and Childbirth's Trials Register, including the detailed search strategies for CENTRAL, MEDLINE, Embase, and CINAHL, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service, please follow this link to the editorial information about Cochrane Pregnancy and Childbirth in the Cochrane Library and select the '***Specialized Register***' section from the options on the left side of the screen.
Briefly, Cochrane Pregnancy and Childbirth's Trials Register is maintained by their Information Specialist and contains trials identified from:

1. monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE (Ovid);
3. weekly searches of Embase (Ovid);
4. monthly searches of CINAHL (EBSCO);
5. handsearches of 30 journals and the proceedings of major conferences;
6. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Search results are screened by two people and the full-text of all relevant trial reports identified through the searching activities described above is reviewed. Based on the intervention described, each trial report is assigned a number that corresponds to a specific Pregnancy and Childbirth review topic (or topics), and is then added to the Register. The Information Specialist searches the Register for each review using this topic number rather than keywords. This results in a more specific search set which has been fully accounted for in the relevant review sections (Included studies; Excluded studies; Studies awaiting classification; Ongoing studies).
See: Dyson 2005 and Fairbank 1999 for details of searching carried out in the previous versions of this review.

Searching other resources

We scanned reference lists of all relevant papers retrieved.
We did not apply any language or date restrictions.

Data collection and analysis

For methods used in the previous versions of this review, see Dyson 2005 and Fairbank 1999.
For this update we used the following methods when assessing the reports identified by the updated search.

Selection of studies

In this update, two review authors (CDG, OOB) independently assessed for inclusion all the potential studies we identified as a result of the search strategy. We resolved any disagreement through discussion or, if required, we consulted a third person (SM).

Data extraction and management

We designed a form to extract data. For eligible studies, four review authors (EJOS, CDG, OOB, EO) extracted the data using the agreed form. For studies published in abstract form only, we attempted to find full reports where available, or contacted authors to provide same. We excluded abstracts for which full reports could not be found. We resolved discrepancies through discussion or, if required, we consulted SM. EJOS entered the data into Review Manager 5 software and checked for accuracy (RevMan 2014). When information regarding any of the above was unclear, we attempted to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Four review authors independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We resolved any disagreement by discussion.

(1) Random sequence generation (checking for possible selection bias)

We described for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.
We assessed the method as:

- low risk of bias (any truly random process, e.g. random number table; computer random number generator);
- high risk of bias (any non-random process, e.g. odd or even date of birth; hospital or clinic record number);
- unclear risk of bias.

(2) Allocation concealment (checking for possible selection bias)

We described for each included study the method used to conceal allocation to interventions prior to assignment and assessed whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.
We assessed the methods as:

- low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk of bias.

(3.1) Blinding of participants and personnel (checking for possible performance bias)

We described for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We considered that studies are at low risk of bias if they were blinded, or if we judged that the lack of blinding would be unlikely to affect results. We assessed blinding separately for different outcomes or classes of outcomes.
We assessed the methods as:

- low, high, or unclear risk of bias for participants;
- low, high, or unclear risk of bias for personnel.

(3.2) Blinding of outcome assessment (checking for possible detection bias)

We described for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. We assessed blinding separately for different outcomes or classes of outcomes.
We assessed methods used to blind outcome assessment as:

- low, high, or unclear risk of bias.

(4) Incomplete outcome data (checking for possible attrition bias due to the amount, nature, and handling of incomplete outcome data)

We described for each included study, and for each outcome or class of outcomes, the completeness of data, including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported and the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information is reported, or can be supplied by the trial authors, we re-included missing data in the analyses which we undertook.
We assessed methods as:

- low risk of bias (e.g. no missing outcome data; missing outcome data balanced across groups);
- high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; 'as-treated' analysis done with substantial departure of intervention received from that assigned at randomisation);
- unclear risk of bias.

(5) Selective reporting (checking for reporting bias)

We described for each included study how we investigated the possibility of selective outcome reporting bias and what we found.
We assessed the methods as:

- low risk of bias (where it is clear that all of the study's prespecified outcomes and all expected outcomes of interest to the review have been reported);

- high risk of bias (where not all of the study's prespecified outcomes have been reported; one or more reported primary outcomes were not prespecified; outcomes of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
- unclear risk of bias.

(6) Other bias (checking for bias due to problems not covered by (1) to (5) above)

We described for each included study any important concerns we have about other possible sources of bias.

We assessed whether each study was free of other problems that could put it at risk of bias:

- low risk of other bias;
- high risk of other bias;
- unclear whether there is risk of other bias.

(7) Overall risk of bias

We made explicit judgements about whether studies are at high risk of bias, according to the criteria given in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we consider it is likely to impact on the findings. We explored the impact of the level of bias through undertaking sensitivity analyses - *see* Sensitivity analysis.

Assessment of the quality of the evidence using the GRADE approach

For this update, we assessed the quality of the evidence using the GRADE approach as outlined in the GRADE handbook, in order to assess the quality of the body of evidence relating to the following primary outcomes for the main comparisons: 1. Healthcare professional-led breastfeeding education and support versus standard care; and 2. Non-healthcare professional-led breastfeeding education and support versus standard care.

1. Initiation of breastfeeding.
2. Early initiation of breastfeeding (within one hour after birth).

We used GRADEpro Guideline Development Tool to import data from Review Manager 5 to create 'Summary of findings' tables (RevMan 2014). We produced a summary of the intervention effect and a measure of quality for each of the above outcomes using the GRADE approach. The GRADE approach uses five considerations (study limitations, consistency of effect, imprecision, indirectness, and publication bias) to assess the quality of the body of evidence for each outcome. The evidence can be downgraded from 'high quality' by one level for serious (or by two levels for very serious) limitations, depending on assessments for risk of bias, indirectness of evidence, serious inconsistency, imprecision of effect estimates, or potential publication bias.

Measures of treatment effect

Dichotomous data

For dichotomous data, we presented results as summary risk ratios (RRs) with 95% confidence intervals (CIs).

Continuous data

For continuous data, we used the mean difference if outcomes were measured in the same way between trials. We planned to use the standardised mean difference to combine trials that measured the same outcome but used different methods to measure the outcome.

Unit of analysis issues

Cluster-randomised trials

We included cluster-randomised trials in the analyses along with individually-randomised trials. We used the effect estimates and uncertainty range from the cluster trials to perform the meta-analysis using the generic inverse variance approach for the meta-analysis of dichotomous outcomes where trials using cluster-randomisation techniques were included (Alderson 2004). Further, we conducted a sensitivity analysis to investigate the effects of randomisation unit.

Other unit of analysis issues

We did not include cross-over trials in this review.

Dealing with missing data

For included studies, we noted levels of attrition. We explored the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis. For all outcomes, we carried out analyses, as far as possible, on an intention-to-treat basis, i.e. we attempted to include all participants randomised to each group in the analyses, and all participants were analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial was the number randomised minus any participants whose outcomes are known to be missing.

Assessment of heterogeneity

We assessed statistical heterogeneity in each meta-analysis using the Tau^2, I^2 and Chi^2 statistics. We regarded heterogeneity as substantial if I^2 was greater than 30% and either Tau^2 was greater than zero, or there was a low P value (less than 0.10) in the Chi^2 test for heterogeneity.

Assessment of reporting biases

In future updates, if there are 10 or more studies in a meta-analysis, we will investigate reporting biases (such as publication bias) using funnel plots. We will assess funnel plot asymmetry visually and if asymmetry is suggested by a visual assessment, we will perform exploratory analyses to investigate it.

Data synthesis

We carried out statistical analysis using the Review Manager 5 software (RevMan 2014). We used fixed-effect meta-analysis for combining data where it was reasonable to assume that studies were estimating the same underlying treatment effect, i.e. where trials were examining the same intervention, and the trials' populations and methods were judged sufficiently similar. If there was clinical heterogeneity sufficient to expect that the underlying treatment effects differed between trials, or if substantial statistical heterogeneity was detected, we used random-effects meta-analysis to produce an overall summary if an average treatment effect across trials was considered clinically meaningful. The random-effects summary was treated as the average range of possible treatment effects and we discuss the clinical implications of treatment effects differing between trials. If the average treatment effect was not clinically meaningful, we did not combine trials.

Where we used random-effects analyses, the results are presented as the average treatment effect with 95% CIs, and the estimates of T^2 and I^2.

Subgroup analysis and investigation of heterogeneity

When we identified substantial heterogeneity, we investigated it using subgroup analyses and sensitivity analyses. We considered whether an overall summary was meaningful, and if it was, used random-effects analysis to produce it.

We planned to carry out the following subgroup analyses for primary outcomes.

1. Low-income (or minority-ethnic) population versus the general population.

We assessed subgroup differences by interaction tests available within Review Manager 5 (RevMan 2014). We reported the results of subgroup analyses quoting the $\chi 2$ statistic and P value, and the interaction test I^2 value.

Sensitivity analysis

We carried out sensitivity analysis to explore the effects of trial quality and type of randomisation on initiation of breastfeeding. We included only trials with 'adequate' rating on allocation concealment; we considered these trials to be of high quality. We also carried out sensitivity analysis by excluding cluster-randomised trials and comparing the results of cluster-randomised trials with the individually-randomised trials.

RESULTS

Description of studies

This review aimed to evaluate the effectiveness of interventions which aim to encourage women to breastfeed in terms of changes in the number of women who start to breastfeed and in terms of those who initiate breastfeeding within the first hour after birth.

Results of the search

We examined 215 reports corresponding to 159 trials. We included 28 trials and excluded 125. Four trials are ongoing (Kimani-Murage 2013; NCT02084680; ISRCTN23019866; Williams 2015), and two are awaiting classification (Bakhshi 2015; Samieizadeh 2011).

Included studies

Twenty-eight trials published between 1987 and 2016 involving 107,362 women met the inclusion criteria for this review, exploring the outcome of initiation of breastfeeding and early initiation of breastfeeding (within one hour after birth). See Characteristics of included studies table. Outcome data was contributed by 23 trials involving 104,238 participants. Of these 23 trials, 18 were individually-randomised studies and five were cluster-randomised studies. Five trials met the inclusion criteria for this review but did not have usable outcome data and were thus excluded from the analyses (Caulfield 1998; Edwards 2013b; Ickovics 2007; Ickovics 2016; Sandy 2009).

Participants

Twenty of the 23 studies contributing data for the analyses and reporting breastfeeding initiation included a total of 27,865 participants. For one trial (Lindenberg 1990), it was unclear how many participants were randomised to each study arm. Together, the three cluster-randomised trials reporting early initiation of breastfeeding included 76,373 participants. Of the 20 trials reporting breastfeeding initiation, 14 were purposefully conducted among low-income or deprived populations (Brent 1995; Chapman 2004; Chapman 2013; Coombs 1998; Edwards 2013a; Efrat 2015; Hill 1987; Kellams 2016; Lindenberg 1990; MacArthur 2009; Reeder 2014; Ryser 2004; Serwint 1996; Srinivas 2015), and six studies did not specifically target low-income or deprived populations (Forster 2004; Hoddinott 2009; Muirhead 2006; Nolan 2009; ISRCTN47056748; Wambach 2011). Three were conducted among specific ethnic subgroups; two recruited from Latina or Hispanic populations (Chapman 2004; Efrat 2015), and one recruited African-American women (Edwards 2013a). Although other studies did not report that they specifically recruited ethnic subgroups, two trials conducted in the USA reported that their sample comprised predominately African-Amer-

ican women (Coombs 1998; Wambach 2011). Other population subgroups targeted by breastfeeding promotion interventions included women undergoing an elective, repeat caesarean section (Nolan 2009), overweight and obese women (Chapman 2013), and adolescents (Wambach 2011). The majority of the 20 trials reporting breastfeeding initiation were conducted among women of mixed feeding intentions antenatally; however, three trials were conducted only among mothers who intended to breastfeed antenatally (Chapman 2004; Chapman 2013; Reeder 2014), and one trial was conducted only among mothers who intended to formula feed or were unsure of how they intended to feed their infant (Ryser 2004).

Interventions

Seven trials evaluated the effect of education and support provided by non-healthcare professionals (Chapman 2004; Chapman 2013; Edwards 2013a; Efrat 2015; MacArthur 2009; Sandy 2009; Srinivas 2015), compared with standard care on breastfeeding initiation among low-income or minority-ethnic populations. Five trials evaluated the effect of breastfeeding education and support compared with standard care (as defined by individual trialists) on breastfeeding initiation (Brent 1995; Hill 1987; Ryser 2004; Serwint 1996; ISRCTN47056748). Four trials evaluated the effect of breastfeeding education using multimedia compared with standard care on breastfeeding initiation (Caulfield 1998; Coombs 1998; Edwards 2013b; Kellams 2016). Three trials evaluated the effect of education and support provided by non-healthcare professionals compared with standard care on early initiation of breastfeeding (Flax 2014; Kirkwood 2013; Lewycka 2013). Two trials evaluated the effect of education and support provided by non-healthcare professionals compared with standard care on breastfeeding initiation among the general population (Muirhead 2006; Reeder 2014). Two trials evaluated the effect of breastfeeding education delivered by healthcare professionals combined with peer support, compared with standard care and compared with an attention control intervention (Forster 2004; Wambach 2011). The attention control intervention in Wambach 2011 was similar to the experimental group interventions in the amount of content and timing, but did not focus on breastfeeding. Two trials evaluated the effect of early mother-infant contact compared with standard care on breastfeeding initiation (Lindenberg 1990; Nolan 2009). Two trials evaluated the effect of group-based care to individualised care (Ickovics 2007; Ickovics 2016). One trial evaluated the effect of additional community-based breastfeeding support groups compared with no additional community-based breastfeeding support groups on the rate of breastfeeding initiation (Hoddinott 2009).

Outcomes

Twenty trials evaluated the effect of an intervention in terms of the numbers of women who ever initiated breastfeeding: Brent 1995; Chapman 2004; Chapman 2013; Coombs 1998; Edwards 2013a; Efrat 2015; Forster 2004; Hill 1987; Hoddinott 2009; Kellams 2016; Lindenberg 1990; MacArthur 2009; Muirhead 2006; Nolan 2009; Reeder 2014; Ryser 2004; Serwint 1996; ISRCTN47056748; Srinivas 2015; Wambach 2011. Three included studies evaluated the effect of an intervention in terms of the numbers of women who initiated breastfeeding early, i.e. within one hour after birth: Flax 2014; Kirkwood 2013; Lewycka 2013. Five studies did not contribute outcome data (Caulfield 1998; Edwards 2013b; Ickovics 2007; Ickovics 2016; Sandy 2009), but were included in the review.

Settings

Of the 25 trials reporting initiation of breastfeeding, 19 were conducted in the USA (Brent 1995; Caulfield 1998; Chapman 2004; Chapman 2013; Coombs 1998; Edwards 2013a; Edwards 2013b; Efrat 2015; Hill 1987; Ickovics 2007; Ickovics 2016; Kellams 2016; Nolan 2009; Reeder 2014; Ryser 2004; Sandy 2009; Serwint 1996; Srinivas 2015; Wambach 2011), four were conducted in the United Kingdom of Great Britain and Northern Ireland (Hoddinott 2009; MacArthur 2009; Muirhead 2006; ISRCTN47056748), and one was conducted in Nicaragua (Lindenberg 1990). Of the three trials reporting early initiation of breastfeeding, one was conducted in Malawi (Lewycka 2013), one in Nigeria (Flax 2014), and one in Ghana (Kirkwood 2013).

Excluded studies

We excluded 125 reports from this review (see Characteristics of excluded studies). Seventy-eight of these reports were not concerned with activity intended to increase breastfeeding initiation rates. Thirty reports did not describe a RCT or their was insufficient information about the study design. Eight reports described interventions that took place after birth, eight reports described interventions that did not target the population of interest to this review, and for one trial, breastfeeding promotion was not part of the intervention. We excluded one trial included in the previous version of this review and one trial awaiting classification in the previous version from this current version (Howard 2000; Wolfberg 2004). Howard 2000 did not involve an intervention for promoting breastfeeding initiation, while Wolfberg 2004 was a breastfeeding promotion intervention targeted at fathers.

Risk of bias in included studies

We conducted an assessment of studies for potential sources of selection, performance, attrition and detection bias, and overall risk of bias (as recommended by Higgins 2011) are detailed in Characteristics of included studies.

See Figure 1 and Figure 2 for a summary of 'Risk of bias' assessments.

Figure 1. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

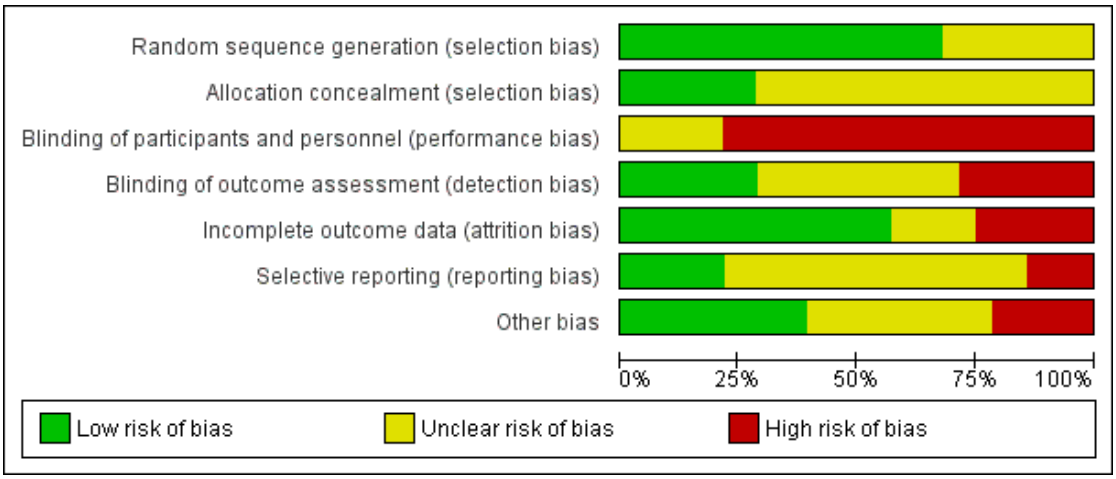
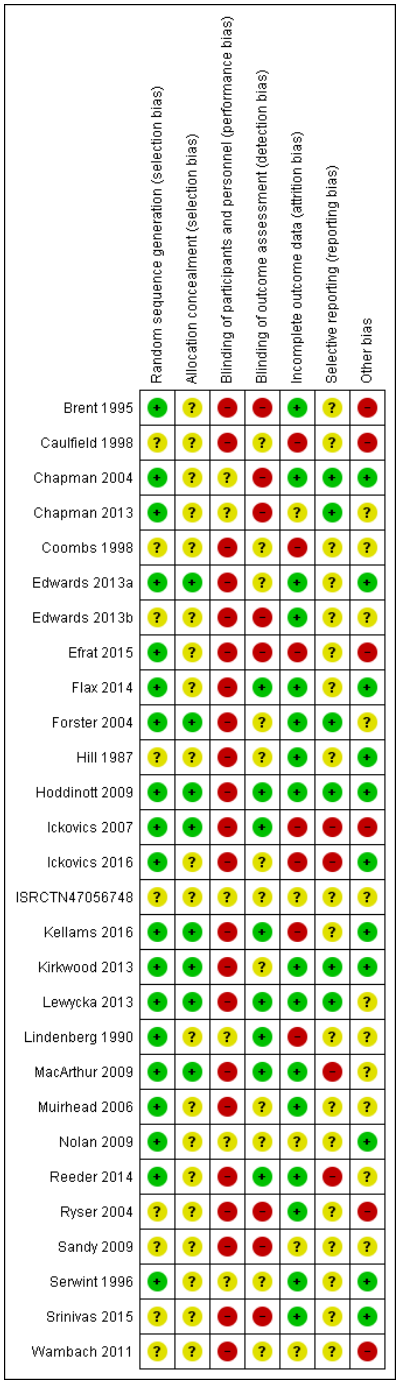


Figure 2. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.



Allocation

Sequence generation

In terms of methods used for random sequence generation, we assessed over 65% (n = 19) of the 28 studies as having low risk of bias, while the risk of bias was unclear for the remaining nine studies.

Allocation concealment

We only judged eight of the 28 included studies as adequately concealing allocation to treatment groups and therefore we considered them to be at low risk of bias; we assessed 20 as having unclear allocation concealment.

Blinding

Performance blinding for this type of intervention is problematic as the women receiving the interventions and the staff delivering them are likely to have been aware of group allocation. Consequently we did not assess any studies as being of low risk of performance bias; we deemed six studies to be at unclear risk and 22 studies at high risk.

In the case of detection bias, the objective nature of the outcome being assessed, namely, whether a woman starts to breastfeed or not at a predefined time point, limits the scope for potential influence by the assessor, regardless of their being blind to the participant's group allocation. However, response bias is possible where outcomes are self-reported. We deemed eight studies to be of low risk of bias, 12 were unclear and eight studies had high risk of detection bias.

Incomplete outcome data

In seven studies there was significant loss to follow-up of more than 20%, or the groups were not balanced or an 'as-treated' analysis was done leading to assessments of high risk of attrition bias. We assessed 16 of the studies to be of low risk of attrition bias and five studies to be of unclear risk of attrition bias.

Selective reporting

For most of the studies we did not have access to either trial registration or the study protocol from which we could judge selective reporting. This resulted in an unclear risk of bias for selective reporting in nearly 65% of studies (n = 18). Of the remaining 10 studies for which we had information about a priori outcomes, we assessed six as having low risk of reporting bias and four as having high risk of reporting bias.

Other potential sources of bias

Any other concerns are noted in the Characteristics of included studies tables that include information about the judgements made on the risk of bias. We assessed six studies to be at high risk of bias from other sources, mainly due to differences in baseline characteristics between experimental and control groups. In two studies (Efrat 2015; Ryser 2004), these differences related to infant-feeding intentions. We judged 11 studies to have low risk of bias from other sources, while 11 had unclear risk of bias from other sources.

Effects of interventions

See: **Summary of findings for the main comparison** Healthcare professional-led breastfeeding education and support versus standard care; **Summary of findings 2** Non-healthcare professional-led breastfeeding education and support versus standard care

Statistical analyses for the primary outcomes of initiation of breastfeeding and early initiation of breastfeeding (within one hour after birth) are reported below for 23 trials involving 104,238 women. We analysed studies within seven comparisons, including Analysis 1.1, Analysis 2.1, Analysis 2.2, Analysis 3.1, Analysis 4.1, Analysis 5.1, Analysis 6.1 and Analysis 7.1.

See Summary of findings for the main comparison and Summary of findings 2 for each of the main comparisons.

1. Healthcare professional-led breastfeeding education and support versus standard care

The trials involving breastfeeding education delivered by healthcare professionals included the following interventions: breastfeeding education and support provided during the prenatal and postpartum periods (Brent 1995; ISRCTN47056748); a breastfeeding lecture, including questions and answers (Hill 1987); breastfeeding promotion campaigns (Ryser 2004); and counselling (Serwint 1996). Breastfeeding education was provided in formal settings.

Initiation of breastfeeding: there was evidence for improved breastfeeding initiation among women who received interventions from healthcare professionals (average risk ratio (RR) 1.43, 95% confidence interval (CI) 1.07 to 1.92; 5 trials, 564 women; $Tau^2 = 0.07$, $I^2 = 62\%$; Analysis 1.1; low-quality evidence). Studies included in this analysis did not report early initiation of breastfeeding.

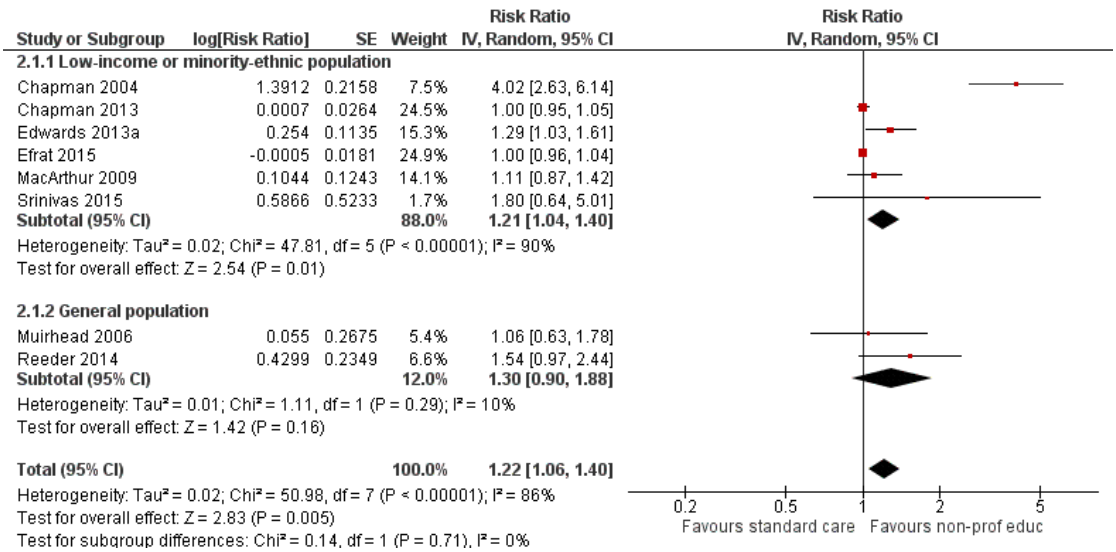
2. Non-healthcare professional-led breastfeeding education and support versus standard care

The trials involving breastfeeding education delivered by non-healthcare professionals included the following interventions: peer

support services provided in addition to routine care (Chapman 2004; MacArthur 2009; Muirhead 2006); peer counselling (Lewycka 2013; Reeder 2014; Srinivas 2015); specialised breastfeeding peer counselling (Chapman 2013); services from paraprofessional doulas (Edwards 2013a); lactation educators (trained research assistants) who implemented phone-based breastfeeding education and support (Efrat 2015); trained credit officers who led monthly breastfeeding sessions (Flax 2014); and home visits by community-based surveillance volunteers during pregnancy and in the first week of life (Kirkwood 2013).

Initiation of breastfeeding: There was evidence for improved breastfeeding initiation among women who received interventions delivered by non-healthcare professional counsellors and in support groups (average RR 1.22, 95% CI 1.06 to 1.40; 8 trials, 5712 women; Tau² = 0.02, I² = 86%; Analysis 2.1; low-quality evidence). We found considerable heterogeneity in this analysis and conducted a subgroup analysis based on low-income/minority population and general population. There was no evidence of a differential effect of the interventions based on low-income/minority population or the general population (test for subgroup differences: Chi² = 0.14, df = 1 (P = 0.71), I² = 0%). We conducted sensitivity analysis by excluding studies with high attrition bias (Chapman 2004; Chapman 2013; Efrat 2015). The overall direction of the effect remained unchanged in favour of non-healthcare professional-led breastfeeding education and support. Additionally, statistical heterogeneity was no longer present when we excluded studies with high attrition bias from the analysis (average RR 1.23, 95% CI 1.06 to 1.43; 8 trials, 5712 women; Figure 3)

Figure 3. Sensitivity analysis (excluding high attrition bias studies) of forest plot of comparison: 2 Non-healthcare professional-led breastfeeding education and support versus standard care, outcome: 2.1 Initiation of breastfeeding.



Early initiation of breastfeeding: Three studies evaluated the effect of non-healthcare professional-led breastfeeding education on early initiation of breastfeeding (Flax 2014; Kirkwood 2013; Lewycka 2013). When all three trials were included in the meta-analysis, there was a positive but non-statistically significant increase in the number of women practicing early initiation of breastfeeding (average RR 1.70, 95% CI 0.98 to 2.95; 3 trials, 76,373 women; Tau² = 0.18, I² = 78%; Analysis 2.2; low-quality evidence). We observed considerable heterogeneity in this analysis.

3. Healthcare professional-led breastfeeding education with non-healthcare professional support versus standard care

Two trials involved both breastfeeding education delivered by healthcare professionals and peer support provided to mothers (Forster 2004; Wambach 2011). Wambach 2011 involved a Theory of Planned Behaviour-based education and counselling intervention delivered by a lactation consultant (registered nurse)-peer counsellor team. The interventions were compared to standard

care or breastfeeding education delivered by healthcare professionals not focused on breastfeeding (attention control) - see below 4. Healthcare professional-led breastfeeding education with peer support versus attention control).

Initiation of breastfeeding: In both trials randomising 1371 mothers (with data available for 895 women in analysis) (Forster 2004; Wambach 2011), there was no evidence of any effect on the initiation of breastfeeding among mothers for breastfeeding education delivered by healthcare professionals with peer support versus standard care (average RR 1.06, 95% CI 0.88 to 1.27; 2 trials, 895 women; Analysis 3.1). This study did not report early initiation of breastfeeding.

4. Healthcare professional-led breastfeeding education with peer support versus attention control

In one study involving 390 adolescent mothers (with data available for 237 women) (Wambach 2011), there was no evidence of any effect on the initiation of breastfeeding among adolescent mothers for breastfeeding education delivered by healthcare professionals with peer support versus attention control (RR 1.21, 95% CI 0.97 to 1.51; 1 trial, 237 women; Analysis 4.1). This study did not report early initiation of breastfeeding.

5. Breastfeeding education using multimedia versus routine care

Two trials involving the use of multimedia to provide breastfeeding education included the following interventions: the use of a self-help manual seven weeks before delivery designed to communicate simple breastfeeding skills to pregnant women compared to usual breastfeeding instructions (Coombs 1998); and a low-cost breastfeeding education video shown to women prenatally versus control (Kellams 2016).

Initiation of breastfeeding: There was no evidence for improved breastfeeding initiation among women following breastfeeding education interventions using multimedia (average RR 1.16, 95% CI 0.63 to 2.41; 2 trials, 497 women; $Tau^2 = 0.18$, $I^2 = 93\%$; Analysis 5.1). We found considerable heterogeneity between the two studies included in this analysis. Studies included in this analysis did not report early initiation of breastfeeding.

6. Early mother-infant contact versus standard care

Two trials that promoted mother-infant contact following either vaginal or caesarean delivery were included in this analysis (Lindenberg 1990; Nolan 2009). In both studies, women who received the intervention were compared with the control group.

Initiation of breastfeeding: There was no evidence for improved breastfeeding initiation among women with increased mother-infant contact compared to women who received usual care (RR 1.08, 95% CI 0.97 to 1.20; 2 trials, 309 women; Analysis 6.1). Studies included in this analysis did not report early initiation of breastfeeding.

7. Community-based breastfeeding groups versus no breastfeeding groups

One trial on community-based breastfeeding groups increased the number of breastfeeding groups available to pregnant and breastfeeding women in intervention localities and compared these to control localities who did not change the number of breastfeeding support groups available to pregnant and breastfeeding women (Hoddinott 2009). They found no difference in rates of any breastfeeding at birth in the intervention clusters compared to the control clusters (mean difference (MD) -0.01, 95% CI -0.05 to 0.03; 1 trial, 18,603 women; Analysis 7.1). The trialists adjusted the data for pre-intervention breastfeeding rates and also for clustering. This trial did not report early initiation of breastfeeding.

ADDITIONAL SUMMARY OF FINDINGS [Explanation]

Population: women exposed to interventions intended to promote breastfeeding
Setting: USA, UK, Nigeria, Ghana, Malawi
Intervention: non-healthcare professional-led breastfeeding education and support
Comparison: standard care

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with standard care	Risk with non-health-care professional-led breastfeeding education and support				
Initiation of breastfeeding	Study population		average RR 1.22 (1.06 to 1.40)	5712 (8 RCTs)	⊕⊕◯◯ LOW [1,2]	It is not possible to blind this type of intervention and so we have not downgraded for lack of blinding
	120 per 1000	147 per 1000 (127 to 168)				
Early initiation of breastfeeding	Study population		average RR 1.70 (0.98 to 2.95)	76,373 (3 RCTs)	⊕⊕◯◯ VERY LOW [1,2,3]	It is not possible to blind this type of intervention and so we have not downgraded for lack of blinding
	5 per 1000	9 per 1000 (4 to 16)				

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

CI: confidence interval; **RCT**: randomised controlled trial; **RR:** risk ratio.

GRADE Working Group grades of evidence
High quality: We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[1] Most studies were unclear for allocation concealment and some studies were of high risk for attrition bias. Downgraded for risk of bias (-1).

[2] High heterogeneity I^2 > 80% (-1).

[3] Wide 95% CI crossing the line with no effect (-1).

DISCUSSION

Summary of main results

This updated review considered the evidence of the effect of interventions aimed to promote the initiation of breastfeeding, taking place before the first breastfeed. The review includes 28 studies published from 1987 to 2016. In total, 107,362 women from seven countries participated in the studies included in this review. The majority of studies were conducted in high-income countries; specifically, Australia (1 study), the USA (19 studies), and the UK (4 studies), although many of these studies did specifically target low-income populations. Three studies were conducted in lower middle-income countries (Ghana, Nicaragua, and Nigeria), and one study was conducted in a low-income country (Malawi). Although the majority of studies were conducted in high-income populations, only 25% of the 107,362 women included in the review were from high-income countries as the study from Malawi was very large, with 55,931 participants (Lewycka 2013).

All of the studies conducted in high-income settings and the study conducted in Nicargua evaluated whether the intervention had an effect on the number of women who ever initiated breastfeeding. Only three of the 28 studies (the studies conducted in the other non-high income countries) evaluated whether the intervention had any effect on the number of women who initiated breastfeeding early (i.e. within one hour of birth).

Of those studies contributing data, the nature of the intervention varied between studies. Specifically, five studies evaluated the effect of breastfeeding education and support provided by healthcare professionals. Eleven studies evaluated the effect of education and support provided by non-healthcare professionals (i.e. peer/lay support). Of these, nine were conducted in low-income or ethnic minority populations, and two were conducted in the general population. Two studies examined combined healthcare professional and non-healthcare professional support. Two trials examined the effect of multimedia breastfeeding education programmes, and another two trials examined the effect of early mother-infant contact. Finally, one trial examined the effect of additional community-based breastfeeding support groups. It should also be noted that even within the same intervention type, the actual components of the intervention also varied. In particular, delivery of the non-healthcare professional education and support included: education and support provided by peer supporter/counsellors (Chapman 2004; Chapman 2013; Lewycka 2013; MacArthur 2009; Muirhead 2006; Reeder 2014; Srinivas 2015), para-professional doulas (Edwards 2013a), trained research assistants (Efrat 2015), trained credit officers (Flax 2014), and community-based surveillance volunteers (Kirkwood 2013).

The pooled data of the five studies (containing 564 women) examining the effect of health education interventions delivered by healthcare professionals indicated that health education interventions delivered by healthcare professionals had a modest effect on increasing the number of women who initiated breastfeeding at any point. However, it should be noted that there was substantial heterogeneity (i.e. differences between the studies in terms of either intervention, population, study design, or outcomes) which may be a result of differences in intervention components or the characteristics of the participants. For instance, four studies evaluated programmes delivered in the USA to low-income women with a range of feeding intentions and where baseline breastfeeding rates are typically low (Brent 1995; Hill 1987; Ryser 2004; Serwint 1996). Despite variation in programme components, all forms of health education delivered by healthcare professionals appeared to have beneficial effects in terms of breastfeeding initiation.

The eight studies (containing 5712 women) that we combined in a meta-analysis to evaluate the effect of education and support delivered by non-healthcare professionals provide evidence for a modest improvement of breastfeeding initiation at any time point. Again, there was a high level of heterogeneity in this analysis. Six of these studies were conducted in low-income populations, which may call into question the generalisability of the results. However, when we compared studies of general populations with low-income populations, we did not find any differences.

When we combined the three studies (containing 76,373 women) that evaluated the effect of non-healthcare professional support on early breastfeeding initiation, we did not identify any evidence of an effect. This analysis also suggested a high level of heterogeneity. When we excluded Flax 2014 from the analysis, a trial with possible selection bias, there was a statistically significant increase in the number of women who practiced early initiation of breastfeeding and no evidence of heterogeneity.

Two studies examined the effect of combined healthcare professional-led education with telephone peer support (Wambach 2011), or community educator (Forster 2004). The intervention for Wambach 2011 was specifically targeted at adolescent mothers (n = 390) and did not demonstrate any effect on breastfeeding initiation. Similarly, there was no evidence of an intervention effect in the studies which looked at multimedia based interventions. This included one trial of a self-help manual of 200 women (Coombs 1998), and one trial of a breastfeeding video of 522 women (Kellams 2016).

The two studies that examined the effect of early mother-infant contact immediately after vaginal birth (Lindenberg 1990), and following caesarean section (Nolan 2009), showed no evidence of effect on breastfeeding initiation specifically. However, the literature on the promotion of the duration of breastfeeding provides clear evidence of the benefits of ongoing mother and infant contact during the hospital stay to support the mother's ability to breastfeed (Moore 2012).

Finally, Hoddinott 2009 was the one study that examined the effect of providing new, additional community-based breastfeeding support groups in low-income areas compared to existing breastfeeding groups; it found no effect on breastfeeding initiation.

Overall completeness and applicability of evidence

This updated review now contains 28 studies, out of which 23 studies contribute data to the review. The number of women included in the review has increased considerably from 1553 in the previous version of the review (Dyson 2005), to 107,362 in this update; this in part is driven by a very large study conducted in Malawi, which included 55,931 women (Lewycka 2013). Therefore, whilst the majority of studies in this review were conducted in high-income countries (Australia, USA, and UK), the majority of participants were from low- and middle-income countries (over 70% of all women). The studies in the USA tended to be small and only involved a total of 5566 women. They also generally targeted specific low-income or disadvantaged groups. The high preponderance of trials from the USA raises questions about the applicability of the findings to other settings.

The interventions tested across the studies included in this review were very diverse. For example, the educational interventions delivered by healthcare professionals included several distinct approaches: a series of one-to-one sessions with a lactation consultation (Brent 1995); a 40-minute lecture with time for questions (Hill 1987); and one session with a paediatrician that covered a range of topics, of which breastfeeding was just one (Serwint 1996). Standard care was also diverse across the included studies and, in the case of the UK where breastfeeding support is part of standard postnatal care, it is perhaps not surprising that some interventions did not have an effect above and beyond that of standard care. For example, in one trial (ISRCTN47056748), women in both experimental and control groups received care that met UNICEF Baby-Friendly standards and included a two-hour antenatal breastfeeding education class. Another trial assessed community-based support groups in a community where existing breastfeeding support groups were available for control group participants (Hoddinott 2009.

Caution is needed in interpreting the findings of the two trials on early mother-infant contact (Lindenberg 1990; Nolan 2009). Generalisation of the results is not recommended due to the moderate quality and size of the studies, and to fundamental concerns regarding the practice of routine separation of mother and infant prior to hospital discharge in the case of Lindenberg 1990, and separation following caesarean section in Nolan 2009.

Quality of the evidence

Overall, we judged the methodological quality of the studies included in this review to be mixed. While we assessed over 65% of the studies to have low risk of bias for generating randomisation sequence, we only judged seven studies to have adequately concealed group allocation. This raises concerns regarding the effect of selection bias on study findings.

Given that there are genuine pragmatic considerations when delivering and evaluating breastfeeding promotion interventions, the ability to effectively blind participants and personnel and thereby reduce performance bias is limited. It is therefore unsurprising that we assessed all 28 studies as having high or unclear risk of performance bias. This should be recognised as an inherent weakness of this particular type of evidence base, rather than of the particular studies included in this review. Of more concern is that we assessed 20 studies to have high or unclear risk of detection bias. Even where there was blinding of outcome assessment, there is a risk of response bias in self-reported outcomes where participants were not blinded.

Incomplete outcome data was also a source of possible bias in this review as we assessed only 16 of the studies as having low risk of attrition bias. The remaining 12 studies either had high rates of loss to follow-up or failed to report attrition clearly. To minimise the effect of this, we conducted all analyses on the basis of intention-to-treat. However, it is possible that this approach may dilute the actual effect of the interventions.

We only assessed six studies as being at low risk of bias for selective outcome reporting; we judged four at high risk and 18 at unclear risk. The high number judged as unclear risk was due to the lack of protocols or trial registration detailing prespecified outcomes.

We assessed six studies as having a high risk of bias from other sources, including differences in baseline characteristics (Brent 1995; Caulfield 1998; Efrat 2015; Ickovics 2007; Ryser 2004; Wambach 2011). Specifically, in the study by Efrat 2015, women in the experimental group had a significantly higher intention to breastfeed than those in the control group. Similary, in the study by Ryser 2004, more participants in the experimental group were undecided about feeding decisions, while more participants in the control group planned to formula feed. Of the remaining studies, we assessed 11 to be of low risk of bias and 11 to be of unclear risk of bias from other sources.

We assessed the quality of the evidence in this review using the GRADE approach (Atkins 2004). See Summary of findings for the main comparison and Summary of findings 2. For the comparison of healthcare professional-led breastfeeding education and support versus standard care, we assessed the quality of evidence for the outcome of initiation of breastfeeding as low (Summary of findings for the main comparison). We downgraded the quality of evidence due to design limitations for most of the studies that contributed data and also high statistical heterogeneity (I^2 more than 60%). For the comparison of non-healthcare professional-led breastfeeding education and support versus standard care, there was also low-quality evidence for the outcome of any initiation of breastfeeding due to design limitations in trials (unclear allocation concealment and high risk for attrition bias) and again high heterogeneity (Summary of findings 2). We also deemed early initiation of breastfeeding to be of very low-quality of evidence; downgraded due to lack of blinding, high heterogeneity and imprecision that was demonstrated with a wide 95% CI that crossed the line with no effect (Summary of findings 2).

Potential biases in the review process

Bias can potentially be introduced at any stage of the review process. To minimise this, two review authors independently screened studies for inclusion and any disagreements were resolved by a third review author. Data extraction and 'Risk of bias' assessments were performed by one review author and then checked by a second review author. Again, any discrepancies were resolved by a third review author. 'Risk of bias' assessment is subjective in nature and therefore another team of review authors may have graded studies differently. To minimise language bias, we translated any study not reported in English into English, and included it in the review, providing it met the inclusion criteria. Whilst we attempted to identify all the evidence on interventions for the initiation of breastfeeding (including published abstracts from conference proceedings) and followed up ongoing studies, it is feasible that relevant research which is unpublished or not registered in a clinical trials register could have been missed.

Agreements and disagreements with other studies or reviews

Consistent with this review, other reviews have reported that interventions including (Jolly 2012; Rollins 2016; Sinha 2015): health education and counselling provided by healthcare professionals; education provided by non-healthcare professionals; and peer support, can increase both the number of women who ever initiate breastfeeding and those who initiate breastfeeding within the first hour after birth. Other reviews provide additional evidence regarding the implementation of such interventions. For example, interventions that are delivered in a combination of settings (e.g. home and community, or health systems and community) are more effective than those delivered in one setting only (Sinha 2015). Additionally, Beake 2012 reported that in health system settings where breastfeeding initiation rates are low, structured programmes of interventions may be most effective (Beake 2012). Moreover, Pérez-Escamilla 2016 found a dose-response between the number of Baby Friendly Hospital Initiative (BFHI) steps women are exposed to and the likelihood of improved breastfeeding outcomes, including early breastfeeding initiation. The use of new technologies may also be an area for future development, with one study in the review by Rollins 2016 suggesting that mass or social media promotion of breastfeeding potentially has a major effect on early initiation of breastfeeding.

AUTHORS' CONCLUSIONS

Implications for practice

Health education and counselling provided by healthcare professionals and peer support interventions included in this review are likely to result in some improvements in breastfeeding initiation rates, particularly among low-income or minority-ethnic women in the USA, where baseline breastfeeding rates are typically low. Similarly, breastfeeding interventions provided by non-healthcare professionals could lead to improvements in rates of early initiation of breastfeeding in low-income countries.

The type of education or support intervention which may be most likely to increase initiation rates appears to be needs-based, one-to-one, informal sessions delivered in the antenatal or perinatal period by a trained breastfeeding professional or peer counsellor. This review update mainly included studies conducted in the USA among low-income women, thus generalisability may be limited to populations of similar characteristics.

Breastfeeding education using multimedia may not be an effective breastfeeding promotion strategy particularly among low-income women.

Early mother-infant contact for women with vaginal or caesarean deliveries was not effective in improving breastfeeding initiation rates. Enabling mothers and infants to remain together for 24 hours a day, 'rooming-in,' is one of the Ten Steps of the UNICEF/WHO Baby Friendly Hospital Initiative (BFHI) adopted as a global programme to support successful breastfeeding and demonstrated to increase initiation rates for all women in all settings.

Implications for research

The majority of the studies included in this review were conducted in the USA and the effectiveness of interventions reviewed here needs to be assessed widely in diverse countries and settings, in studies that are adequately powered, have adequate methods of randomisation, adequate reporting of losses to follow-up, and utilise intention-to-treat analysis.

Publication of evaluations of effectiveness should detail the content and method of the intervention delivered; the people (e.g. peer or healthcare professional) who delivered it and the training and experience these people had; baseline breastfeeding rates for the study-site population; and feeding intention for participants within each comparison group.

Future research should aim to evaluate the effectiveness of the intervention to improve both the initiation and duration of any and/or exclusive breastfeeding at least up to six months to enable appropriate planning and implementation of interventions during pregnancy and the postnatal period. In addition, studies need to provide clear descriptions of both the intervention and study outcomes.

Further research to evaluate interventions that combine health education or support before the birth with support during the days immediately after the birth should be evaluated and compared with those that offer education alone.

Further research into early mother-infant contact regardless of mode of delivery, followed by rooming-in until hospital discharge is needed to evaluate the effect of early mother-infant contact on increasing breastfeeding initiation rates among various population groups.

Studies are needed to help women to find ways to overcome societal barriers to breastfeeding, including policy-level interventions.

Good-quality research to evaluate the effectiveness of breastfeeding promotion and support on breastfeeding rates among maternity and community services who achieve fully accredited BFI/BFHI status would further inform policy and practice.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Brent 1995

Methods	Randomisation by permuted block. Analysis was by intention-to-treat.
Participants	108 English-speaking, nulliparous, pregnant women attending a prenatal clinic, regardless of infant-feeding preference were recruited into study. Participants stratified by age into 3 groups (less than 20, 20-29, or at least 30 years)
Interventions	Experimental group: (N = 51). Breastfeeding education and support provided throughout the prenatal and postpartum periods and into the first year of the child's life. Education consisted of 2 to 4 individual 10 to 15-minute sessions with a lactation consultant discussing the benefits and practice of breastfeeding. Content of sessions was based on the women's needs and interests. After delivery, mothers were followed up with daily inpatient rounds by the lactation consultant. Further follow-up consisted of a telephone call 48 hours after discharge, a visit to the lactation clinic at 1 week and lactation consultation present at each health supervision visit until weaning or when the infant was 1 year of age, whichever came first. Professional education was directed at nursing and medical staff who interacted with the breastfeeding dyad Control group: (N = 57). Routine care, consisting of optional prenatal breastfeeding classes; postpartum breastfeeding instruction by nurses and doctors; outpatient follow-up in the paediatric ambulatory department
Outcomes	Incidence of breastfeeding in hospital. Incidence of breastfeeding at 2 weeks. Incidence of breastfeeding at 2 months. Incidence of breastfeeding at 6 months. Median duration of breastfeeding. Subgroup analysis for women who indicated at the first prenatal visit that they planned to formula feed or were undecided
Notes	To determine if a comprehensive breastfeeding promotion programme increased the incidence and duration of breastfeeding in a low-income population

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Patients, stratified by age were randomised into the intervention and control groups by using a blocked randomisation procedure ….randomisation was performed in block sizes of 8, pg 799

Brent 1995 (*Continued*)

Allocation concealment (selection bias)	Unclear risk	Unclear whether allocation concealment was adequate. Allocation of participants to either intervention or control groups was not clearly described. According to the authors, "patients were randomised into the intervention and control groups by using a blocked randomisation procedure". They say further that "patients assigned to the intervention group required a minimum of two prenatal lactation consultations to be included in the sample". It is unclear if this criteria was an overall eligibility criteria for the study or if it was applied to the intervention group, pg 799
Blinding of participants and personnel (performance bias) All outcomes	High risk	Inadequate due to non-blinded study. Intervention was conducted by lactation consultant who also administered the questionnaires
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome assessors were not blinded to group allocations. "Data were collected by questionnaire that were administered in person, not blinded by the lactation consultant at the first prenatal visit…". Outcome data were reported by mothers and it is possible that reports may have been biased
Incomplete outcome data (attrition bias) All outcomes	Low risk	Adequate, breastfeeding initiation reported for all 108 women in the study. Although the study tables could not be read easily because it was darkened during production, the participant numbers seem balanced and reasons were provided for exclusions made from the intervention group
Selective reporting (reporting bias)	Unclear risk	Study protocol was not available to assess the prespecified outcomes
Other bias	High risk	Mothers in the intervention group were found to have had an increased rate of complications of pregnancy compared to the control group. This may reflect some fundamental differences in the characteristics of the women in both groups, pg 780

Caulfield 1998

Methods	Method of allocation of the 4 clinics: 4 slips of paper labelled with 1 of 4 clinics randomly selected from pot for centralised allocation to a pre-ordered list of comparison groups Analysis was not by intention-to-treat.
Participants	4 clinics administered through the Johns Hopkins University WIC programme, that had similar rates for ethnicity (90.4% to 96.1% African-American) and breastfeeding rates at 1 month (2.0% to 5.9% in 1991) Women were recruited between April 1992 and January 1994 as they registered for prenatal care at the 4 clinics. 674 women were eligible. 242 had complete data (36%) and only these were included in the results. Differences were noted by clinic in parity, education and employment status before and during pregnancy of the included women
Interventions	2 x 2 factorial design. Control (N = 57). Routine WIC services and nutrition education. Video intervention (N = 64). Breastfeeding motivational video, based on Best Start video, consisted of 8 trigger vignettes 2 to 5 minutes in length, about benefits of and major benefits to breastfeeding, played continuously in the waiting area without staff supervision. Discussion with service provider following video was encouraged. Posters displayed in clinic areas and relevant sites Peer counselling intervention (N = 55). Women interested in breastfeeding received personalised information and support on breastfeeding issues of concern specific to each participant. Women received counselling 3 times during pregnancy. WIC counsellors were former WIC clients, had successfully breastfed and completed 5-week training programme. Video and peer counsellor (N = 66). All the components described above
Outcomes	Breastfeeding initiation. Breastfeeding initiation by infant-feeding intention at enrolment Breastfeeding at 7 to 10 days for those who initiated.
Notes	Not included in the meta-analysis on statistician's advice, because with only 1 clinic in each group, it is not possible to calculate the standard error of difference

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of sequence generation not described. Information limited to "four clinics were randomly assigned to control and treatment groups."
Allocation concealment (selection bias)	Unclear risk	Allocation concealment procedures not described. Information limited to "four clinics were randomly assigned to control and treatment groups."

Caulfield 1998 (*Continued*)

Blinding of participants and personnel (performance bias) All outcomes	High risk	It is not stated whether mothers and personnel were blinded. However, given the nature of the intervention it would not have been possible to blind staff
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Data were collected by trained interviewers but it is not stated whether the interviewers were blinded
Incomplete outcome data (attrition bias) All outcomes	High risk	548 women were enrolled in the study and 273 remained in the study to the end, so 50.2% were lost to follow-up
Selective reporting (reporting bias)	Unclear risk	No protocol or evidence of predefined outcomes to judge this domain
Other bias	High risk	Baseline differences in parity, education, and employment status before and during pregnancy, between women enrolled at each clinic

Chapman 2004

Methods	Recruiter not the same as peer counsellors. Computerised random allocation of weekly cases: appears to be on-site but not stated. Data entry of cases likely to be Research Assistant who recruited but not likely to know how case would be allocated as SPSS random selection Analysis was by intention-to-treat. Data collection on infant-feeding practices, sources of breastfeeding support and demographics via face-to-face or telephone interviews by a researcher during the hospital stay or monthly calls thereafter
Participants	Pregnant women attending Hartford Hospital, Connecticut, USA, on 1 of 3 days a week when recruitment conducted between July 2000 and August 2002. Inclusion (prenatal) over 18 years old, considering breastfeeding, low-income. Inclusion (postpartum) healthy full-term singleton infant, no maternal history of HIV. Exclusion: infants admitted to special care.
Interventions	Control group (N = 75). Routine prenatal breastfeeding education consisted of individualised breastfeeding information offered in response to women's questions, and written breastfeeding materials from the prenatal clinic. Routine perinatal breastfeeding education included hands-on assistance and education from maternity ward nurses, written breastfeeding materials and access to an International Board Certified Lactation Consultant for breastfeeding problems. Intervention group (N = 90). In addition to routine care as for control group, prenatal, perinatal (and postnatal)

	peer support services, consisting of at least 1 prenatal home visit to review benefits of breastfeeding, screen for inverted nipples, discuss breastfeeding myths, positioning and anticipatory guidance. Breastfeeding video viewed if possible. Additional prenatal visits if necessary 47/89 (53%) reported a prenatal home visit with the mean visit lasting 69.0 (standard deviation 57.6) minutes. Participants recall of the prenatal visit was: written brochures provided (38/42); breastfeeding positions reviewed (37/42); breast pumping information provided (31/42); breastfeeding video viewed (19/42); breastfeeding myths reviewed (38/42)
Outcomes	Breastfeeding initiation. Breastfeeding at 1 month and 3 months.
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Participants were randomised to either the control group or the intervention group by means of a computer software programme. Cases were entered into a data file weekly, and SPSS randomly selected, approximately 50%, pg 898
Allocation concealment (selection bias)	Unclear risk	It is unclear how allocation concealment was preserved.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participant and personnel blinding was not described in the text. In the discussion, authors say the study was not double-blind but no details are provided regarding the extent of blinding that was done
Blinding of outcome assessment (detection bias) All outcomes	High risk	Authors of this report say that "interviewers were unaware of group assignment at the beginning of each interview".... pg 901, but failed to give details of how blinding was done and the extent to which interviewers were blinded given the above comment
Incomplete outcome data (attrition bias) All outcomes	Low risk	Approximately 20% of participants were lost to follow-up in intervention group and > 20% loss to follow-up in control group. However, the reasons for dropout was similar across both groups. Fig. 1

Chapman 2004 (*Continued*)

Selective reporting (reporting bias)	Low risk	Primary outcomes reported in study protocol was exclusive breastfeeding rate (time frame: 3 months postpartum) while secondary outcomes were breastfeeding rate (time frame: 3 months postpartum) and breastfeeding initiation rate (time frame: for the duration of the hospital stay, average equals 3 days). however, study report included different primary outcomes than planned and more secondary outcomes were reported
Other bias	Low risk	The study appears to be free of other sources of bias.

Chapman 2013

Methods	Individual RCT, 206 pregnant, overweight/obese, low-income women and randomly assigned them to receive SBFPC or standard care. Random allocation was done using computer software "Each week, the study coordinator used SPSS software to randomly assign 50% of newly recruited participants to the intervention group" All analyses were by intention-to-treat.	
Participants	206 pregnant, overweight/obese, low-income women <= 36 weeks' gestation. To be eligible for the trial, women had to be considering breastfeeding and have a prepregnancy BMI >= 27.0, >= 18 years, <= 36 weeks' gestation, singleton pregnancy, absence of medical conditions interfering with breastfeeding, planning to remain in the area for 6 months postpartum, income, 185% of the federal poverty level, and having telephone access	
Interventions	SBFPC intervention promoting exclusive breastfeeding among overweight/obese, low-income women delivered during prenatal visits, postpartum after delivery, and up to 6 months postpartum. Control group received standard care which included Breastfeeding: Heritage and Pride (BHP)	
Outcomes	Primary outcomes - breastfeeding initiation and the rates of exclusive and any breastfeeding at 2 weeks, 1 month, 3 months, and 6 months postpartum. Secondary outcomes included infant morbidity (diarrhoea, otitis media, emergency department visits, hospitalisation), maternal amenorrhoea, and breastfeeding intensity	
Notes		
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Chapman 2013 (*Continued*)

Random sequence generation (selection bias)	Low risk	Random allocation was done using computer software "Each week, the study coordinator used SPSS software to randomly assign 50% of newly recruited participants to the intervention group", e163
Allocation concealment (selection bias)	Unclear risk	It is unclear how allocation concealment was preserved, e163
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participant and personal blinding was not described in the text, e163
Blinding of outcome assessment (detection bias) All outcomes	High risk	Data collectors were not completely blinded. "The interviewer was not informed of participants' group assignment but was not completely blinded", e164
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Approximately 20% of participants were lost to follow-up in intervention group and > 20% loss to follow-up in control group, e165
Selective reporting (reporting bias)	Low risk	Primary outcomes reported in study protocol was exclusive breastfeeding rate (time frame: 3 months postpartum) while secondary outcomes were breastfeeding rate (time frame: 3 months postpartum) and breastfeeding initiation rate (time frame: for the duration of the hospital stay, average equals 3 days). however, study report included different primary outcomes than planned and more secondary outcomes were reported
Other bias	Unclear risk	Baseline characteristics of participants were different wherein the intervention group was significantly younger and differed in delivery mode, compared with controls, e165

Coombs 1998

Methods	Allocation method was an opaque container filled with 100 tags (50 - experimental group; 50 - control group). Following greater selection of women to the control group, a statistician calculated the number of control tags to be removed to bias further selection in favour of intervention tags until groups were balanced Analysis was not by intention-to-treat.
Participants	200 pregnant women, age 18 years or more, literate, no medical conditions likely to make breastfeeding difficult, willing to consider using the manual and to undertake interview about breastfeeding Those who agreed to participate after the interview differed significantly from those who declined in terms of parity, breastfeeding knowledge, attitudes, confidence, and intention to breastfeed
Interventions	Experimental group (N = 104). Received the self-help manual 7 weeks before delivery during standard prenatal breastfeeding counselling from nutritionist. The manual was modelled on successful self-help smoking cessation interventions to reduce cigarette smoking among low-income pregnant women using cognitive behavioural theory. Received a total of 2 prenatal interviews and 2 postnatal interviews. Control group (N = 96). Standard prenatal breastfeeding counselling from nutritionist. No manual. Received a total of 2 prenatal interviews and 2 postnatal interviews
Outcomes	Exclusive breastfeeding at hospital discharge or if breastfeeding initiated later, exclusive breastfeeding within 1 week
Notes	To determine if a self-help manual assisted low-income pregnant women to prepare for, initiate and maintain breastfeeding

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"immediately following enrolment, the women were randomised into either the treatment of control group". No further details regarding how randomisation was achieved was provided, pg 204
Allocation concealment (selection bias)	Unclear risk	No descriptions were given regarding allocation concealment.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Inadequate due to non-blinding. Participants were not blinded to treatment group and authors discuss the bias arising from participants knowledge of study group status before intervention (manual distribution), pg 207

Coombs 1998 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not clear if those assessing outcomes were blind to group allocation. The study outcomes were assessed by maternal self-report through interviews but authors do not say if outcome assessors were blinded or not
Incomplete outcome data (attrition bias) All outcomes	High risk	Inadequate, 23/104 lost from the intervention group and the study involved 200 women who were randomised to either the treatment or control group (treatment - 96, control - 104). Overall, there was a 25% attrition rate (23 dropout in treatment group (24%) and 26 (25%) in the control group) . Reasons for dropout were provided in the text, but could not be compared across groups as only aggregate percentages were provided, pg 204-205, fig 1 26/96 from the control group (24.5% overall)
Selective reporting (reporting bias)	Unclear risk	Study protocol was not available to assess the prespecified outcomes
Other bias	Unclear risk	The baseline characteristics of study participants were not described in sufficient detail to be able to assess if there were differences between women enrolled in the treatment and control groups

Edwards 2013a

Methods	Individual RCT of community doula home visiting. Doulas provided home visits and support during childbirth. Data were obtained from medical records and maternal interviews at birth and 4 months postpartum. Intent-to-treat analysis used
Participants	Low-income, African-American mothers (n = 248) under the age of 22 years. Participants were recruited when they were less than 34 weeks pregnant and if they were planning to deliver at the affiliated hospital
Interventions	Intervention-group mothers received services from paraprofessional doulas: specialised home visitors trained as childbirth educators and lactation counsellors. Doulas provided home visits from pregnancy through 3 months postpartum, and support during childbirth. Mothers in the community doula intervention group received an average of 10 prenatal and 12 postpartum home visits. A doula was present at the hospital for the birth for 81.5% of the intervention group infants. Control group mothers received usual care
Outcomes	Infant-feeding practices including breastfeeding initiation, breastfeeding duration, timing of introduction of complementary foods

Notes		
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomisation took place in blocks of 4, 6, or 8, with equal numbers assigned to the intervention and control groups within each block. A biostatistician prepared a set of opaque envelopes, each labelled with a subject ID number and containing a group assignment. Comment: prepared by a biostatistician, likely random sequence generation. Information obtained from the 'Randomisation' section, pg S162
Allocation concealment (selection bias)	Low risk	"A biostatistician prepared a set of opaque envelopes, each labelled with a subject ID number and containing a group assignment." Information obtained from the 'Randomisation' section, pg S162
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and researchers were not blinded to group allocation. Information obtained from the Randomisation section, pg S162
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Data on breastfeeding attempts were collected by mother report at the hospital the second morning after the birth and from review of the nursing notes in the mother's medical chart after the mother's discharge. Comment: unclear if research staff were blinded to group assignment. Information obtained from the Outcome measures section, pg S163
Incomplete outcome data (attrition bias) All outcomes	Low risk	Only 1 participant lost to follow-up in each group. Information obtained from Figure 1, pg S164
Selective reporting (reporting bias)	Unclear risk	Trial was registered 2 weeks before the paper was accepted for publication. Retrospective registration so a priori outcomes unclear
Other bias	Low risk	No other obvious bias.

Edwards 2013b

Methods	This is a pilot/feasibility individual RCT to explore the acceptability of a multi-racial, computer-animated, female, laptop-based Computer Agent designed to improve exclusive breastfeeding rates among mothers interested in breastfeeding. The Computer Agent was modelled on a live counterpart, an International Board Certified Lactation Consultant. The setting for the intervention was primarily the outpatient offices of Obstetricians/Gynaecologists affiliated with the USA-based hospital
Participants	15 participants (7 in the intervention group, 8 in the control group) completed this study. Eligible women were primiparas, in their third trimester of pregnancy with a singleton fetus, 18 years of age or older, English-speaking, had internet access, and were interested in breastfeeding
Interventions	Control arm: the control arm received the standard care relating to breastfeeding. At the time of this study, that included an optional prenatal breastfeeding class, information on the benefits of breastfeeding from obstetric offices, encouragement to put the baby to the breast within the first hour of life, education by all staff on management of breastfeeding, and lactation consultations once per day or more as needed Intervention arm: the intervention arm received all aspects of the control arm, plus access to the Computer Agent to access additional information about breastfeeding. The Computer Agent was used prenatally during a third trimester office visit and perinatally at hospital discharge. The Computer Agent was designed to present breastfeeding information and support focusing on the benefits of breastfeeding and motivational interviewing techniques prenatally. Dialogue was customised to each participant and the programme maintained memory of the subject's demographics (name, baby's name and sex)
Outcomes	Intent to exclusively breastfeed, attitudes toward breastfeeding (as measured by the Iowa Infant Feeding Attitudes Scale), breastfeeding self-efficacy (as measured by the Breastfeeding Self-Efficacy Scale Short Form)
Notes	This Cochrane Review does not include outcome data from this primary research article

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The authors state that they used "blocked randomization, with a blocking factor of 4" (pg 1964) but do not describe the random sequence generation
Allocation concealment (selection bias)	Unclear risk	The authors state that they used "sealed envelope[s]" (pg 1964). It is unclear whether these envelopes were opaque
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the intervention, it would not be possible to blind participants. The authors describe the distribution and utilisation of the tablet laptops in physicians' offices prenatally as "somewhat cum-

Edwards 2013b (*Continued*)

		bersome." This was problematic for office staff. It is unclear whether these office staff were part of the research team. If the researchers were managing the distribution of the tablet laptops, there is potential for performance bias to be introduced
Blinding of outcome assessment (detection bias) All outcomes	High risk	The authors state (pg 1965) that when subjects participating in the study were admitted to the hospital, the "study staff visited them on the birth day of their baby to complete questionnaires and access the Computer Agent (if assigned to that arm)." This description suggests that study staff collecting data were aware of study-arm allocation. All enrolled participants were also visited by study staff at hospital discharge to collect outcome data
Incomplete outcome data (attrition bias) All outcomes	Low risk	Outcome data are available for 13 of the 15 participants.
Selective reporting (reporting bias)	Unclear risk	No protocol or evidence of predefined outcomes to judge this domain
Other bias	Unclear risk	No other obvious sources of bias.

Efrat 2015

Methods	Individual RCT. Lactation educators (undergraduate students who completed a semester-long lactation education course and 10 hours of post-course training) developed a relationship with women prenatally and then phoned mothers regularly postnatally. Data relating to the factors associated with breastfeeding were collected during the third trimester. Breastfeeding outcome data were collected at 72 hours, 1 month, 3 months, and 6 months postpartum. Outcome data were collected by research assistants who used a phone questionnaire to collect data from the control and intervention group participants
Participants	289 pregnant, low-income Hispanic women. Women were 26-34 weeks' gestation at recruitment, medicaid recipients, self-identified Hispanic, available via telephone, and not already assigned to a WIC peer counsellor
Interventions	Lactation educator-implemented prenatal and postpartum phone-based breastfeeding education and support. The intervention entailed 4 prenatal and 17 postpartum phone calls (first call initiated when mothers were in the third trimester of pregnancy and the last call when mother was 6 months postpartum). The intervention participants were also provided with the lactation educator's phone number so they could contact her more frequently if need be

Efrat 2015 (*Continued*)

Outcomes	Breastfeeding initiation, duration, and exclusivity.	
Notes		

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"… randomised to either the control or intervention group using computer software. " Comment: the authors do not specify that the sequence was computer-generated but it likely was. Information pg 427
Allocation concealment (selection bias)	Unclear risk	Unclear whether investigators could predict group allocation
Blinding of participants and personnel (performance bias) All outcomes	High risk	Research assistants and mothers were not blinded to treatment allocation
Blinding of outcome assessment (detection bias) All outcomes	High risk	The study protocol prohibited research assistants from providing the control group participants with any breastfeeding education or support and also required that they use the same data collection strategy techniques when collecting data from participants in both groups. Comment: as previously mentioned, research assistants were not blinded to treatment allocation. Information pg 427
Incomplete outcome data (attrition bias) All outcomes	High risk	Unclear why there are data for breastfeeding initiation for 80 control and 77 intervention mothers. 1 reason for dis-enrolling people seems to be "discontinuation of breastfeeding" It is unclear whether the authors have initiation data on these women. Data are missing with no explanation as to who or why is missing
Selective reporting (reporting bias)	Unclear risk	No trial protocol available.
Other bias	High risk	"Despite randomisation, women in the intervention group had a significantly higher intention to breastfeed." Information obtained from the 'Results' section, pg 431

Flax 2014

Methods	Cluster-RCT of an integrated microcredit and community health intervention. Baseline and final survey interviews were conducted by an independent team of trained data collectors unaware of the clients study arm assignment
Participants	461 pregnant women in 79 microcredit groups.
Interventions	The intervention had 3 components. Trained credit officers led monthly breastfeeding learning sessions during regularly scheduled microcredit meetings for 10 months. Text and voice messages were sent out weekly to a cell phone provided to small groups of microcredit clients (5-7women). The small groups prepared songs or dramas about the messages and presented them at the monthly microcredit meetings. The control arm continued with the regular microcredit programme
Outcomes	Outcome variables were as follows: 1) exclusive breastfeeding to 1, 3, and 6 months; 2) initiation of breastfeeding within 1-hour of delivery; and 3) use of only colostrum or breast milk during the first 3 days of life
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Groups were "randomly assigned to intervention and the other to control using a Bernoulli random variable generated by 1 of the researchers." Information obtained from randomisation and eligibility criteria section, pg 1121
Allocation concealment (selection bias)	Unclear risk	The authors specify that "monthly meeting groups with similar numbers of clients and pregnant women were paired, with 1 group randomly assigned to intervention and the other to control..." Comment: the authors do not specify whether investigators could know in advance which study arm a meeting group would be assigned to. Information obtained from randomisation and eligibility criteria section, pg 1121
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants could not be blinded and personnel who delivered the intervention could not be blinded due to the nature of the intervention
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Baseline and final survey interviews were conducted by an independent team of trained data collectors unaware of the

Flax 2014 (*Continued*)

		clients' study arm assignment." Information obtained from 'Data collection procedures' section, pg 1121
Incomplete outcome data (attrition bias) All outcomes	Low risk	"At follow-up, 196 (86%) and 194 (84%) clients remained in the intervention and control arms, respectively." Comment: data available for all live births in intervention group and only missing for 2 live births in control group (1 maternal death, 1 dyad moved away) Information obtained from 'Results' section, 1st paragraph, pg 1122 and Figure 1, pg 1122
Selective reporting (reporting bias)	Unclear risk	Comment: could not locate study on "Current Controlled Trials" so it's unclear what the planned outcomes for this particular analysis were
Other bias	Low risk	No other obvious risk of bias.

Forster 2004

Methods	A computerised system of biased urn randomisation was accessed by telephone by the research midwife after written consent was obtained Analysis undertaken by authors for this review was by intention-to-treat based on data reported by study authors
Participants	Women booking for antenatal care at the Royal Women's Hosptial in Melbourne, Australia, between May 1999 and August 2001. The hospital had been an accredited Baby Friendly hospital since 1995 Inclusion: booking as public patients, having a first child, 16-24 weeks' pregnant at recruitment, able to speak and write in English Exclusion: physical problems that prevented breastfeeding, chose birth centre or private obstetric care
Interventions	Control group (N = 327). Received BFHI accredited standard care. Practical skills intervention (N = 327). In addition to BFHI accredited standard care, received the offer of a single session of 1.5 hours focusing on practical breastfeeding skills. 'Latching on' was explained and demonstrated using dolls and knitted 'breasts'. Breastfeeding complications and management were discussed. Partners were not present Attitudes intervention (N = 327). In addition to BFHI accredited standard care, received the offer of 2 X 1-hour sessions focusing on changing attitudes to breastfeeding. Partners/significant others were encouraged to attend. The first class included information about the advantages of breastfeeding and explored participants' views of breastfeeding and their perceptions of the attitudes

	of others. Between classes participants were encouraged to interview their own and their partner's mother. The second class included a group discussion based on these interviews, and discussion of resources for breastfeeding women. Women were encouraged to write a breastfeeding plan
Outcomes	Breastfeeding initiation. Breastfeeding and exclusive breastfeeding at 6 months.
Notes	Authors concluded that in settings where breastfeeding initiation is high, neither of the interventions could be recommended as effective Results not included in the meta-analysis because we considered the control group, BFHI standard care, had received an intervention that meant we could not compare this control group with the control groups of other studies in the review

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"A computerised system of biased urn randomisation" was used
Allocation concealment (selection bias)	Low risk	A computerised system of biased urn randomisation was accessed by telephone by the research midwife to ascertain women's group allocation. The research midwife telephoned the patient and was asked to follow prompts on the telephone, including inputting the woman's hospital record number. The random allocation was then generated
Blinding of participants and personnel (performance bias) All outcomes	High risk	It is not stated if women or staff were blinded but it is stated that women were given a booklet about the study and the intervention was explained to them
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Data were collected by research midwives and blinding was not described. It is not clear if the same midwife was responsible for allocation and data collection
Incomplete outcome data (attrition bias) All outcomes	Low risk	90.3% follow-up.
Selective reporting (reporting bias)	Low risk	All of the primary outcomes reported in study protocol were reported in the study. The secondary outcomes were reported in a separate paper

Forster 2004 (*Continued*)

Other bias	Unclear risk	A smaller percentage of women in the standard care group received a pension/benefit as the primary family income (7.2% versus 16% and 14.6% in the intervention groups). This difference was not tested for significance

Hill 1987

Methods	Women of different parity were randomised to intervention or control groups Analysis was by intention-to-treat.
Participants	64 women intending to give birth at the study hospital and keep their infant, and who gave birth to a healthy infant, and had a telephone or agreed to return the telephone interview survey by post 95% of the total sample were white women.
Interventions	Experimental group (N = 31). Attended a 40-minute lecture including 5-10 minutes for questions and answers; received a pamphlet with information that reinforced lecture content Control group (N = 33). Routine breastfeeding classes to all women attending antenatal clinic with no lecture, discussion, pamphlet or post-test
Outcomes	Breastfeeding knowledge scores. Breastfeeding outcomes: no breastfeeding, any breastfeeding, breastfeeding less than 6 weeks, breastfeeding more than 6 weeks
Notes	To determine the effects of a breastfeeding education programme among low-income pregnant women in Chicago

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	The authors state "Randomization of each individual in these two subgroups [primipara/multipara] was carried out" but do not specify how the random sequence was generated. Information obtained from 'Method' section, 'Procedure' subsection, pg 149
Allocation concealment (selection bias)	Unclear risk	No details of allocation concealment available.

Hill 1987 (*Continued*)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants could not be blinded to the intervention. It is unclear whether the investigator delivered the intervention, however, the investigator was aware of group allocation as the author states "The investigator decided to administer the posttest immediately after the question and answer period [of the education session] because of availability of the subjects..." Information obtained from 'Method' section, 'Procedure' subsection, pg 149
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The follow-up interview was conducted by a "researcher" but it's not clear if this researcher was blinded to group allocation. Information obtained from 'Method' section, 'Procedure' subsection, pg 150
Incomplete outcome data (attrition bias) All outcomes	Low risk	Breastfeeding initiation data are reported for all participants. Information obtained from Table 2, pg 151
Selective reporting (reporting bias)	Unclear risk	No trial registration data available.
Other bias	Low risk	No other obvious sources of bias.

Hoddinott 2009

Methods	RCT with cluster-randomisation. Unit of randomisation and analysis was locality
Participants	Pregnant women and breastfeeding mothers registered at GPs in 14 localities (of 66) in Scotland who gave birth 2002-4. Birth records supplying data n = 9747 in intervention group and n = 9111 in control group
Interventions	Intervention localities were randomised to a policy aim to double the number of local breastfeeding support groups and to make weekly support groups open to all pregnant women and breastfeeding mothers. The groups were to be facilitated by health professionals taking a woman-centred approach and aiming to provide breastfeeding support and social interaction for women Control localities received no intervention. Breastfeeding support groups existed in some control areas
Outcomes	Any breastfeeding at birth, 5-7 days and 8-9 months after birth and maternal satisfaction were secondary outcomes of the study. The primary outcome was number of babies receiving any breast milk at 6-8 weeks. The study used routinely collected outcome data for the 2 pre-trial years and the 2 post-trial years Results were not presented in a way which allowed us to enter them into data and analysis tables but we have summarised findings in the text

Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Used random number tables.
Allocation concealment (selection bias)	Low risk	"An independent statistician used random number tables to randomise locality pairs to either intervention or control." Central allocation
Blinding of participants and personnel (performance bias) All outcomes	High risk	Staff in intervention localities are likely to have known of the policy intervention and some women in new groups may have known of it. Other staff and other women whose outcome data were analysed may not have known
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Researchers analysing primary and secondary outcomes were reported to be blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	The study authors included all existing routinely collected data in their analyses. Results were not presented in a way which allowed us to enter them into RevMan data and analysis tables but we have summarised findings in the text
Selective reporting (reporting bias)	Low risk	ISRCTN44857041; All the outcomes reported in the registry were reported in the text
Other bias	Low risk	Not known.

Ickovics 2007

Methods	Individual-randomised trial. Women at 2 publicly-funded clinics were randomly assigned to standard individual care or group care
Participants	Pregnant women aged 14-25 years attending 2 large obstetric clinics in university-affiliated hospitals in the USA. African-American women with limited financial resources were over represented, which reflected clinic use patterns Inclusion criteria: less than 24 weeks of gestation, age 25 years or less, no medical problems requiring individualised care as "high-risk pregnancy" (e.g. diabetes, HIV),

	English or Spanish language, and willingness to be randomised. All providers received 2 full days of formal training in Centering Pregnancy group prenatal care Exclusion criteria: not described.
Interventions	Intervention group (n = 394). Group antenatal care provided by a trained practitioner (e.g. midwife, obstetrician). Sessions first involve self-care assessment of blood pressure and weight and individual prenatal assessments by the practitioner. The remainder of the session discussion, education, and skills building to address explicit learning objectives in prenatal care, child birth preparation, and postpartum and parenting roles. The full curriculum consists of 10 x 120-minute sessions. All sessions apart from the initial assessment, cervical assessments in late pregnancy or if health concerns occur, are conducted in this manner Control group (n = 653). Individual care. Details not provided.
Outcomes	Primary outcomes: gestational age at delivery, birthweight. Other outcomes included: adequacy of prenatal care, breastfeeding initiation measured at a 6 month interview, and psychosocial outcomes (pregnancy knowledge, prenatal distress, readiness for labour and infant care, and satisfaction with prenatal care
Notes	Study did not contribute data to the review as the actual number of women who initiated breastfeeding was not reported. Authors contacted but no response

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation sequence.
Allocation concealment (selection bias)	Low risk	"Allocation was concealed from participant and research staff until eligibility screening was completed and study condition was assigned. A computer-generated randomization sequence, password protected to recruitment staff and participants, was used to assign participants."
Blinding of participants and personnel (performance bias) All outcomes	High risk	"..it was not possible to have treatment blinded."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"..all measurement and data collection were conducted in blinded fashion independently of the care setting." The research team members were independent of prenatal care

Ickovics 2007 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	High risk	The number of women in each group at the postpartum interview was not stated. Only the total number of women who took part (n = 783) was reported. This gives a follow-up rate of 74.8% at 6 months. The authors stated there was differential dropout between group and individual care (P = 0. 95)
Selective reporting (reporting bias)	High risk	The study protocol does not specify breastfeeding initiation or satisfaction with prenatal care as outcomes
Other bias	High risk	The original study protocol states this is a 3-arm trial comparing Centrering Pregnancy, Centering Pregnancy Plus and standard care. The study reported only has 2 arms and it is not reported why there is a difference or if the 2 intervention arms were combined There were significant differences between intervention and control group with women in the intervention group having significantly greater history of preterm birth, lower scores for prenatal distress and a contained a higher percentage of African-American women Financial disclosure states that 1 study author receives approx. USD 3000 per year from Centering Pregnancy and Parenting Association Inc and another study author is the executive director of Centering Pregnancy and Parenting Association Inc

Ickovics 2016

Methods	Multisite cluster-randomised trial. Clusters were 4 community health centres and 10 hospitals
Participants	Pregnant adolescents aged 14-21 years attending an prenatal care visit at 1 of the participating clinical sites. The clinical sites were in New York City and predominantly served low-income women Inclusion criteria: pregnancy at less than 24 weeks' gestation, pregnancy not considered high risk, ability to speak English or Spanish, and willingness to participate in group prenatal care Exclusion criteria: not described.

Interventions	Intervention group (n = 610). Centering Pregnancy Plus group prenatal care. First visit is an individual clinical assessment and thereafter all care is provided in a group setting. Sessions were facilitated by a clinician (e.g. obstetrician, midwife) and a co-facilitator (e.g. nurse, medical assistant) . The 10 X 120-minute sessions first involve self-care assessment of blood pressure and weight and individual prenatal assessments by the practitioner. The remainder of the session involves facilitated discussions on many issues related to pregnancy, childbirth, and postpartum. 4 of the sessions specifically focused on activities to improve sexual self-efficacy, HIV knowledge, interpersonal sexual communication, perceived risk, and social norms Control group (n = 623). Individual care. Details not provided.
Outcomes	Primary outcomes included: gestational age, birthweight and breastfeeding initation.It is not stated when this was measured and deviates from the protocol which states that breastfeeding measured at 6 and 12 months is the primary outcome Secondary outcomes: neonatal intensive care unit admission rates and duration of stay, incidence of a sexually transmitted infection 12 months postpartum, rapid repeat pregnancy and sexual risk behaviours
Notes	Does not contribute data to review. Actual numbers of women initiating breastfeeding not reported (only an as-treated odds ratio presented)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was done using a computer-generated sequence in stratified blocks
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not described.
Blinding of participants and personnel (performance bias) All outcomes	High risk	The authors recognise that "neither clusters nor participants could be blinded to study condition"
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Interviews were conducted by providing participants with headphones to spoken questions on a display screen and trained staff reviewed maternal and child medical records to extract data. It is not stated if these staff were blinded
Incomplete outcome data (attrition bias) All outcomes	High risk	93.9% of the intervention group and 92. 3% of the control group were followed up, however, breastfeeding initiation was reported as an as-treated analysis

Ickovics 2016 (*Continued*)

Selective reporting (reporting bias)	High risk	Actual study reports breastfeeding initiation but protocol states breastfeeding at 6 and 12 months as outcomes. Clinical trial registration number: NCT00628771
Other bias	Low risk	Only significant difference at baseline was that women in the intervention group were more likely to be married

ISRCTN47056748

Methods	RCT (n = 182 randomised).
Participants	Inclusion: primigravid women attending for antenatal care at 20 weeks' gestation, intending to give birth at the study hospital Exclusion: women who had started the 'young mums' parentcraft programme prior to the 20 weeks' visit; vulnerable women (e.g. women who did not speak or understand English); mothers separated from their babies The setting was a maternity unit in Northern Ireland with Baby-Friendly accreditation
Interventions	Intervention (89 randomised) Women received a "motivationally enhanced" version of standard care from staff who had been trained in a programme called "Designer Breastfeeding" Standard care (93 randomised). At this study hospital, standard care, received by all the study participants, met Baby-Friendly standards and complied with National Institute for Clinical Excellence (NICE) guidelines, and consisted of a 2-hour antenatal infant-feeding class, a breastfeeding book and midwife support for the first 3 weeks after the birth
Outcomes	The primary outcome of the study was breastfeeding motivation. Breastfeeding initiation, exclusive breastfeeding at discharge, and 3 weeks postpartum were secondary outcomes. Breastfeeding initiation was defined as giving 1 breastfeed or 1 episode of expressed breast milk
Notes	Authors concluded that the study provided preliminary evidence that motivation to breastfeed can be increased through routine instruction

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not described.
Allocation concealment (selection bias)	Unclear risk	The authors provided further detail: "The only way in which we could conceal group allocation at the recruitment phase and yet develop a process by which delivery suite midwives would be able to know 3 months later

ISRCTN47056748 (*Continued*)

		to which of two postnatal environments to transfer the mother and baby" was as follows: "A sampling frame was generated using SPSS 11.5. Numbers 1-250 were entered into the spreadsheet and the following commands selected: Data - Select cases - Random sample of cases - Approximate 50% of cases - Unselected cases filtered (1 intervention group, 0 control group). Groups 1 and 0 were then colour coded. The random sampling output was transferred onto a table with each number replaced with the appropriate colour of sticker to indicate group membership - as women gave consent to participate the next coloured sticker on the sampling frame was placed on her notes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The authors state: "Neither the researcher, nor the research participants could predict their allocated treatment"
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Described as single-blind.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	(Report pg 18 Fig 3) 234 assessed for eligibility, 182 consented and randomised and 144 completed (79%). Dropouts reported by group but not all with reasons. 57/93 (61%) randomised to the intervention were known to have initiated breastfeeding, compared with 53/89 (60%) randomised to the control group
Selective reporting (reporting bias)	Unclear risk	No trial registration is available.
Other bias	Unclear risk	Not enough information to judge.

Kellams 2016

Methods	Individual randomised trial involving 522 low-income women. A computer-generated block randomisation sequence using random block sizes, stratified by prenatal clinic, was used. Sealed, opaque envelopes, which the research assistant opened just prior to loading the video for the participant to view were used to allocate women to groups All analyses were conducted on an intention-to-treat basis.
Participants	522 low-income women of 24 to 41 weeks' gestation who were WIC eligible could participate in the trial. Women were excluded if they had multiple-gestation pregnancy, any known contraindication to breastfeeding (e.g. HIV infection, drug use, or receipt of chemotherapy), or their primary language was not English
Interventions	25-minute educational breastfeeding video (Better Breastfeeding, Injoy Productions, 2008) viewed during the prenatal period in waiting room/examination room while the participant waited to be seen by the physician or nurse practitioner. Control group

	received a 20-minute educational video about nutrition during pregnancy (Healthy Pregnancy Nutrition, Injoy Productions, 2007)	
Outcomes	Primary outcomes: the initiation of breastfeeding and the exclusivity of breastfeeding during the newborn hospital stay	
Notes		

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	A computer-generated block randomisation sequence using random block sizes, stratified by prenatal clinic, was used, pg 154
Allocation concealment (selection bias)	Low risk	Sealed, opaque envelopes, which the research assistant opened just prior to loading the video for the participant to view were used to allocate women to groups, pg 154
Blinding of participants and personnel (performance bias) All outcomes	High risk	Personnel were not blinded to the intervention as viewing of the video was done in the examination and/or waiting room, pg 154
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Data reported were abstracted from medical records, and research assistants abstracting the data were blinded to the participant's group assignment, pg 157
Incomplete outcome data (attrition bias) All outcomes	High risk	Only 64% of eligible women were enrolled in the study and reasons for non participation was not provided, pg 154
Selective reporting (reporting bias)	Unclear risk	Study protocol was not available.
Other bias	Low risk	Although there were some differences in baseline characteristics of participants, these differences are unlikely to influence review outcome of interest. Women in the control group were more likely to live with a partner or other adult while women in the intervention group were more likely to live with a parent, pg 154

Kirkwood 2013

Methods	Cluster-randomised controlled trial designed to test the effect of the home-visits strategy in Ghana delivered by the existing CBSVs. Clusters were made up of districts and towns
Participants	All pregnancies to women of reproductive age (15-45 years) that ended in a livebirth or stillbirth between November 2008 and December 2009, and data for pregnancies, births, and deaths gathered through the surveillance system established for the ObaapaVitA trial of vitamin A and maternal mortality and continued for the Newhints trial were used
Interventions	Training the CBSVs in the 49 intervention zones to identify pregnant women in their community and followed by 2 home visits during pregnancy and 3 visits after birth on days 1, 3, and 7. CBSVs counselled women and their families to promote essential newborn-care practices, weigh and assess babies for danger signs, and refer sick newborn babies as necessary
Outcomes	Primary outcomes were all-cause NMR and coverage of key essential newborn-care practices. Secondary outcomes were age-specific and cause-specific NMRs
Notes	Other outcomes not clearly stated were included in the report. However, protocol indicates CBSVs training/counselling included training on all such behaviour outcomes reported in the article (clinicaltrials.gov/ct2/show/record/NCT00623337) "The primary behaviour outcomes were the percent ages of mothers practising the Newhints recommended behaviours. The data were extracted from the birth form administered at the first surveillance visit after birth; the form included questions about the pregnancy, delivery, and newborn-care practices promoted by Newhints," pg 2187

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Computer-generated restricted randomisation was then done in a one-to-one ratio by an independent epidemiologist using stratified sampling..." pg 2186
Allocation concealment (selection bias)	Low risk	Allocation was done by an independent epidemiologist...pg 2186
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel in the intervention zones were not blinded: "Community-wide meetings were then organised by the district health management and Newhints teams during July and August, 2008, and chaired by the community chiefs. Their purpose was to introduce the importance of newborn care to the community; explain the rationale, content, and structure of the Newhints intervention; discuss the importance of community support for its success; and present the trained CBSVs with their

Kirkwood 2013 (*Continued*)

		Newhints polo shirt, briefcase, and certificate," pg 2186
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	"The data were extracted from the birth form administered at the first surveillance visit after birth..." pg 2187
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data on early initiation of breastfeeding are available for > 96% of liveborn infants in both the intervention and the control group, Table 2
Selective reporting (reporting bias)	Low risk	Although early initiation of breastfeeding wasn't explicitly stated as a secondary outcome in the trial protocol, the content of the 3rd trimester visit of the CBSVs included advice to breastfeed the baby immediately after delivery. Thus, it is clear that this is an outcome the authors were interested in. Trial protocol (published 2010: www.trialsjournal.com/content/11/1/58), Table 1
Other bias	Low risk	No other obvious source of bias.

Lewycka 2013

Methods	2 x 2 factorial cluster-RCT. 48 equal-sized clusters were randomly allocated to 4 groups
Participants	55,931 women in Mchinji district in rural Malawi.
Interventions	1 group received a "women's group" intervention, 1 group received "peer counsellors", 1 group received both interventions and the control group received neither. 24 facilitators guided groups through a community action cycle to tackle maternal and child health problems. 72 trained volunteer peer counsellors made home visits at 5 time points during pregnancy and after birth to support breastfeeding and infant care
Outcomes	Primary outcomes for the women's group intervention were maternal, perinatal, neonatal, and infant mortality rates; and for the peer counselling were infant mortality rates and exclusive breastfeeding rates
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Lewycka 2013 (*Continued*)

Random sequence generation (selection bias)	Low risk	Researchers "...allocated clusters with a random number sequence generated in Stata (version 7.0)". Information obtained from 'Methods, randomisation and masking' section
Allocation concealment (selection bias)	Low risk	Allocation was performed by researchers who were "not involved in the implementation of the intervention". Information obtained from 'Methods, randomisation and masking' section
Blinding of participants and personnel (performance bias) All outcomes	High risk	Masking of allocation was impossible at participant level.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Data were gathered independently of programme implementation. Information obtained from 'Methods, randomisation and masking' section
Incomplete outcome data (attrition bias) All outcomes	Low risk	Volunteer peer counselling group (82.4%) , no intervention group (83%)
Selective reporting (reporting bias)	Low risk	The authors state that they tested the intervention effect on primary and secondary outcomes based on "Previously agreed hypotheses". Information obtained from 'Statistical analysis' section, pg 1726
Other bias	Unclear risk	There were baseline differences between the intervention and control groups post-randomisation. Also, the authors note "[b]ecause women knew their intervention allocation, behavioural answers were open to best behaviour bias" on pg 1734

Lindenberg 1990

Methods	Randomisation using a table of random numbers for the first 3 months. In the 4th month, a 3rd group were assigned consecutively (due to ethical and organisational limitations) to a 2nd intervention group. Results from this group have been excluded from this Cochrane Review due to the lack of randomisation for allocation. Analysis was not by intention-to-treat.
Participants	512 women were randomised and data are reported for 259 women experiencing a normal, vaginal delivery with no complications and living in poor urban areas of Managua, Nicaragua

Interventions	Experimental group. First 3 months of study: 45 minutes of mother-infant contact immediately after birth with standardised (uniform) breastfeeding promotion followed by complete separation until discharge. Standardised breastfeeding promotion consisted of a series of specific breastfeeding promotional messages. Control group. First 3 months of study: complete separation throughout hospitalisation with usual (ad hoc) breastfeeding promotion. Ad hoc breastfeeding promotion consisted of the routine infant-feeding information a mother might receive which, given the large volume of deliveries and short hospital stay, was usually very scant to non-existent
Outcomes	Any breastfeeding at 1 week. Exclusive breastfeeding at 1 week. Any breastfeeding at 4 months. Exclusive breastfeeding at 4 months.
Notes	To examine the effects of early postpartum mother-infant contact, followed by separation until discharge, on the incidence and continuation of breastfeeding

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"The random assignment of study subjects was accomplished using a table of random numbers…" Information obtained from 'Materials and methods' section, 'Design and interventions' subsection, pg 182
Allocation concealment (selection bias)	Unclear risk	It is unclear whether investigators could have predicted which group a new participant would have been allocated to
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear whether blinding of participants and providers for delivery of intervention and standardised care was adequate
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcomes assessors were blind to the "study hypothesis that breastfeeding is a function of early mother-infant contact". Information obtained from 'Materials and methods' section, 'Design and interventions' subsection, pg 182

Lindenberg 1990 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	High risk	27% of the original sample of 512 were lost to follow-up due to "postpartum maternal or infant complications or failure to locate homes for follow-up visits". The breakdown of these reasons for loss to follow-up is not provided. However, it is stated that the "group lost to follow-up was similar to the remaining group of mothers in age and marital status, and were similarly distributed among the three study groups". Information obtained from 'Materials and methods' section, 'Sample' subsection, pg 182
Selective reporting (reporting bias)	Unclear risk	No trial registration is available.
Other bias	Unclear risk	There were no differences in demographic characteristics between groups. However, there were significant differences between the 3 study groups in infant birthweight and height, episiotomy rates, anaesthesia, and premature rupture of the membrane. It is unclear whether these differences may introduce bias. Information obtained from 'Results' section, 'Characteristics of the study population' subsection, pg 183

MacArthur 2009

Methods	RCT with cluster-randomisation. Unit of randomisation: GP antenatal clinic (n = 66) . Randomisation stratified by size of antenatal clinic and by midwifery team (n = 8) providing care at the clinic. Unit of analysis was individual women. Planned sample size ("just under 3000 women") not achieved (data received from 2511 women giving birth)
Participants	All GPe antenatal clinics in 1 Primary Care Trust within a deprived urban area of Birmingham, UK. In this Trust 90% of births (n = 5500 to 6000) were to women from ethnic minority groups, with > 25% to women born outside the UK. Data from women giving birth 1 February to 31 July 2007 were included. 70% of these women were in the lowest 10th for deprivation score
Interventions	Antenatal peer support intervention clusters. The Trust recruited 11 peer support workers for breastfeeding, with personal successful breastfeeding experience of several months and who were, as far as possible, peers of women in the clinics in ethnicity and language. Peer supporters received 8 weeks training, based on the UNICEF baby-friendly breastfeeding management course, that addressed cultural beliefs and barriers appropriate to the local population. The planned level of peer support was an initial introduction in the antenatal clinic followed by at least 2 contacts, at 24-28 and around 36 weeks' gestation, including at least 1 home visit. The purpose

	of the contacts was to provide advice and information in the benefits of breastfeeding and to support women with particular cultural barriers or concerns. The duration of sessions was to be based on need. All pregnant women registered with GP antenatal clinics allocated to the intervention received, in addition to usual care, an offer of contact with a peer support worker Control clusters. Standard antenatal care including usual information and advice from midwives on breastfeeding, without input from community peer support workers
Outcomes	Initiation of breastfeeding defined as "a positive response to whether the infant had had breast milk either at the time of delivery of by the time of hospital discharge, as recorded in the hospital records"
Notes	Type of intervention: antenatal 1:1 peer support contact with individual women

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Randomisation was stratified by size of antenatal clinic and by midwifery team and undertaken using a computer program."
Allocation concealment (selection bias)	Low risk	"Randomisation was undertaken using a computer program by the trial statistician, who was blind to the identity of the antenatal clinics."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible due to the nature of the intervention.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Data on outcome (and characteristics of individual women) were obtained anonymously from the 3 main hospitals where women attending the study clinics gave birth
Incomplete outcome data (attrition bias) All outcomes	Low risk	Women (4%) who gave birth other than in the 3 main hospitals were not included in the results. Among women who gave birth in the 3 hospitals, breastfeeding status was not known for 57/1140 (5%) women from clinics randomised to peer support versus 56/1371 women (4%) from clinics randomised to standard care

MacArthur 2009 (*Continued*)

Selective reporting (reporting bias)	High risk	The trial protocol included 2 secondary outcomes - breastfeeding continuation rate at 10-14 days and 6 weeks and breastfeeding at 6 months. These secondary outcomes were not mentioned in the study report, neither were they reported on
Other bias	Unclear risk	There were few differences in the baseline characteristics of participants in both groups. the intervention group had more deliveries in 1 of the 3 hospitals and fewer African-Caribbean women than the control group

Muirhead 2006

Methods	A 2-group individual RCT. Allocation to control or peer support group was by post-recruitment concealed allocation, separate for each of 4 strata. Sequences for each stratum were generated at the start of the trial by computer in blocks of 10. Allocation to control or peer support group was by post-recruitment concealed allocation Analysis was by intention-to-treat basis.
Participants	225 women at 28 weeks' gestation.
Interventions	Peer support for breastfeeding. Peer supporters visited participants at least once during the antenatal period. Peer support was available to women in the intervention group if they were breastfeeding on returning home from hospital after delivery and if the peer supporters were informed in time. Control groups received normal breastfeeding support only
Outcomes	Breastfeeding initiation and duration.
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Allocation sequences for each stratum were generated at the start of the trial by computer in blocks of 10, pg 193
Allocation concealment (selection bias)	Unclear risk	"Allocation sequences for each stratum were generated at the start of the trial by computer in blocks of 10 (that is, five random allocations to each of the peer support and control groups in each different

		block of 10) to give approximate numerical balance between groups. These lists were never seen by those doing the recruiting. The allocation of each woman was done by postrecruitment telephone call to obtain the next allocation from the lists," pg 193
Blinding of participants and personnel (performance bias) All outcomes	High risk	Authors do not describe blinding but made the following comment: "There was no post-allocation concealment as once a woman was allocated to the peer support or control group this was known to the peer supporters and others associated with the trial," pg 193
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessment was done by maternal self report through questionnaire interviews. Although the trial team were not directly involved in the questionnaire collection, questionnaires were completed in the presence of health practitioner and that may have influenced womens' reporting of the outcome, pg 194
Incomplete outcome data (attrition bias) All outcomes	Low risk	Although reasons for loss to follow-up were not provided, follow-up loss was very low in both groups (n = 5) fig 1
Selective reporting (reporting bias)	Unclear risk	Trial protocol was unavailable to assess prespecified outcomes
Other bias	Unclear risk	The baseline characteristics of participants was comparable and trial appeared to be free of other sources of bias

Nolan 2009

Methods	RCT (pilot study reporting on 50 mother-infant dyads).
Participants	Women scheduled for a planned, repeat, caesarean delivery under regional anaesthesia, of a live singleton at term (at least 37 weeks' gestation), at a USA hospital with approximately 1500 deliveries per year, a 33% caesarean rate and a 10% repeat, elective caesarean rate
Interventions	NIMS intervention. The intervention took place in the operating theatre and during the immediate postoperative period in the obstetric PACU. Protocol components included intra- and postoperative environmental manipulation to maintain a maternal-infant spatial distance of not more than 8 feet, with uninterrupted maternal visual and auditory contact, *en face* pre-

	sentation at birth, intraoperative cheek-to-cheek skin contact, a period of uninterrupted skin-to-skin contact, and mother and infant to be transferred to the PACU together Control. Usual care was not standard. Typically, infants were removed from the operating room promptly after stabilisation and transferred to the PACU in advance of the mother's transfer. Most mothers had brief or no physical contact with their infants. Skin-to-skin contact was not routinely offered in the PACU and initiation of breastfeeding might or might not occur there
Outcomes	Breastfeeding initiation (at birth, by direct observation in the PACU) Breastfeeding at hospital discharge (from medical records). Breastfeeding at 4 weeks (by maternal report to a mail survey question "At 4 weeks of age, was your baby receiving any feedings with breast milk?) The study also reported maternal pain and anxiety and infant temperature, respiratory rate and salivary cortisol levels
Notes	Type of intervention: organisation of care - to minimise maternal-infant separation after repeat elective caesarean birth - not generalisable Initiation of breastfeeding not defined. Outcome data collected as above Outcome data. 72 recruited - not reported by group - include without data. 22 excluded (31%) - not reported by group (6 received general anaesthesia, 2 infants poorly, 14 did not go to the PACU because the PACU was not staffed at the time of the birth) 50 reported, 25 in each group. Breastfeeding initiation: NIMS 20/25 versus control 15/25. Breastfeeding at hospital discharge: NIMS 19/25 versus control 13/25 Breastfeeding at 4 weeks: NIMS 16/25 versus control 8/25.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomisation was by coin toss "Maternal-infant dyads recruited were randomly assigned by the flipping of a coin into control and experimental treatment groups"
Allocation concealment (selection bias)	Unclear risk	Group allocation was by a member of the research team flipping a coin
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not possible due to the nature of the intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessors for breastfeeding initiation and breastfeeding at 4 weeks were not blinded

Nolan 2009 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Analysis was not by intention-to-treat as only those receiving the intervention (that is, those whose caesarean section operations were undertaken when the obstetric postanaesthesia care unit was staffed) were included in the analysis
Selective reporting (reporting bias)	Unclear risk	Study protocol was not available.
Other bias	Low risk	The study appears to be free of other sources of bias.

Reeder 2014

Methods	Participants were randomly allocated to 1 of 3 study arms; no peer counselling, 4 telephone contacts, 8 telephone contacts. Outcomes were reported by mothers to WIC staff who were not part of the study team. Analysis was by intention-to-treat
Participants	1948 WIC clients recruited during pregnancy who intended to breastfeed or were considering breastfeeding. There were no exclusions on the basis of age, multiple gestations, or previous birth history
Interventions	Women assigned to the low-frequency peer counselling group were scheduled to receive 4 planned, peer-initiated contacts: the first after initial prenatal assignment, the second 2 weeks before the expected due date, and the third and 4th at 1 and 2 weeks postpartum. Women in the high-frequency contact group received 4 additional calls at months 1, 2, 3, and 4. The control group received no peer counselling
Outcomes	Breastfeeding initiation, duration, and exclusivity.
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"The forms were sorted between Spanish- and English-speaking clients, after which they were randomly allocated to 1 of 3 study arms by using a computer-generated random number function." Information obtained from 'Methods' section, 'Enrolment' subsection
Allocation concealment (selection bias)	Unclear risk	Information not available in primary article or supplementary material

Reeder 2014 (*Continued*)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants not blinded, peer counsellors not blinded.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcomes were reported by mothers to WIC staff who were not part of the study team. The study team then collected those data. In the supplementary material, the authors clarify that peer counsellors (the investigators who were unblinded) had no access to outcome data. WIC staff collected breastfeeding outcome data at regular visits, investigators did not have access
Incomplete outcome data (attrition bias) All outcomes	Low risk	Less than 10% loss to follow-up per group. Outcome data for breastfeeding initiation available for 585/635 controls (92.1%), 591/625 intervention group 1 (94.6%), 611/625 intervention group 2 (97.8%)
Selective reporting (reporting bias)	High risk	Authors stated that their goal was to increase breastfeeding initiation, duration and exclusivity but did not report breastfeeding initiation in the paper
Other bias	Unclear risk	Appears to be more loss to follow-up in the control group.

Ryser 2004

Methods	Random assignment by participants selecting a sealed envelope (not sequentially numbered, opacity not specified) to determine assignment to intervention or control group. Analysis was by intention-to-treat
Participants	54 English speaking pregnant women of 18 years or more, literate, eligible for Medicaid, access to telephone and stated feeding intention of 'bottle (formula) feed' or 'undecided' Marital status and intention to formula feed differed significantly between comparison groups
Interventions	Experimental group (N = 26). Received the Best Start Program (Bryant 1990), presented as a breastfeeding promotion campaign that aims to allow health professionals to examine women's misconceptions and educate them about their specific concerns. It has been marketed since 1992 and its materials have been used by various programmes, including the SNPWIC Program. In this study, the researcher used the 'Best Start' videotapes, training manuals and handouts to implement the educational programme during 4 prenatal visits (2 more than control group as visits also included data collection phase).

Ryser 2004 (*Continued*)

	Control group (N = 28). No exposure to Best Start Program. No details of routine breastfeeding promotion activities at the physician's office were provided
Outcomes	Any breastfeeding at 1 week postpartum. Attitudes to breastfeeding. Social and professional support.
Notes	To evaluate the effect of the Best Start Program on breastfeeding attitudes, intention and initiation in low-income women

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"Random assignment to groups was accomplished by having the subjects select a sealed envelope to determine their assignment to either the experimental group or the control group." Comment: unclear how the random sequence was generated. Information obtained from 'Methods' section. 'Setting' subsection, pg 302
Allocation concealment (selection bias)	Unclear risk	"Random assignment to groups was accomplished by having the subjects select a sealed envelope to determine their assignment to either the experimental group or the control group." Comment: unclear if envelope was opaque. Information obtained from "Methods" section. "Setting" subsection, pg 302
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants were not blinded due to the nature of the intervention. "All contact with both experimental and control group subjects was conducted by the researcher so that standardization of communication could be optimized." Thus, the researcher was not blinded to group allocation. Information obtained from 'Methods' section. 'Intervention' subsection, pg 302
Blinding of outcome assessment (detection bias) All outcomes	High risk	"The researcher telephoned each subject within 1 week of delivery to ask … 'How did you feed your infant in the hospital?'" The researcher was not blinded to group allocation, as per comments above. Information obtained from 'Methods' section.

Ryser 2004 (*Continued*)

		'Setting' subsection, pg 302
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data reported for 27/28 in the control group and 23/26 in the intervention group. Information obtained from 'Results' section, pg 303
Selective reporting (reporting bias)	Unclear risk	No trial registration is available.
Other bias	High risk	The authors reported that "more experimental group subjects were undecided about feeding decisions and that more subjects in the control group planned to formula feed." Information obtained from 'Results' section, pg 302

Sandy 2009

Methods	The Best Beginnings Program is a primary prevention home-visiting programme. This programme was initially developed as part of the Healthy Families American initiative
Participants	Families from 1 of 2 impoverished, predominately Latino census tracts were eligible to participate in Best Beginnings. Women were eligible to participate if they were pregnant or had a baby $\leq$ 3 months. 588 women were recruited to the study. Of these, 281 met recruitment criteria specific to this analysis: enrolled prenatally, did not drop out prior to their child's birth, had a singleton baby, baby was not in the neonatal intensive care unit, and data were available on infant-feeding practices. Of these 281 mothers, 238 provided data on infant-feeding method within 1-week of birth
Interventions	FSWs provided services to women in both the intervention and control groups through home visits. Women in the intervention group were visited weekly during pregnancy and FSWs provided information about prenatal care and infant-feeding methods. If necessary, FSWs also made referrals for mothers in the intervention group to community agencies for additional support. During the prenatal home visits, mothers in the intervention group received a dedicated breastfeeding promotion intervention that covered many aspects of breastfeeding. Mothers in the control group were visited by FSWs less frequently, they were provided with educational material such as booklets and pamphlets but FSWs did not actively promote breastfeeding among these mothers
Outcomes	Rates of any or exclusive breastfeeding among mothers in the intervention group compared with those not exposed to the prenatal intervention. The authors were not explicit about timing of the outcome measurement in their study aim
Notes	This Cochrane Review does not include outcome data from this primary research article
Risk of bias	

Sandy 2009 (*Continued*)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"[P]articipants were randomly assigned to either a program group or a control group". No further details provided, pg 405
Allocation concealment (selection bias)	Unclear risk	No descriptions provided in the text.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Neither participants not personnel were blinded. Authors considered this a limitation "The lack of double blinding in the present study is a methodological limitation," pg 410
Blinding of outcome assessment (detection bias) All outcomes	High risk	No descriptions were provided on blinding of outcome assessors. "The possibility of systematic experimenter bias exists for mother-reported infant-feeding practices in the present study, since the FSWs (Family Support Workers) who questioned mothers about infant-feeding practices were not blinded to the program versus control group status of mothers. In addition, for some mothers, reports about breastfeeding may have been influenced by a desire to please their FSWs or give the "correct" answer," pg 410
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	There are no data on the outcome of interest.
Selective reporting (reporting bias)	Unclear risk	The study protocol was unavailable.
Other bias	Unclear risk	The characteristics of women in intervention and control groups were not described

Serwint 1996

Methods	Random number table with blocks of 10 to assign participants. Allocation of women to a paediatrician was not completely random as based on paediatrician availability according to mother's due date Analysis undertaken by authors for this review was by intention-to-treat based on data reported by study authors
Participants	156 nulliparous women, > 18 years, between 8 and 28 weeks' gestation, who had not yet selected a paediatrician or wanted their infant to receive paediatric care at the hospital-based paediatric clinic Both experimental and control groups comprised 91% of African-American women

Interventions	Experimental group (N = 81). In addition to routine care, received a scheduled prenatal visit between 32 and 36 weeks' gestation at a hospital-based clinic with the infant's future paediatrician. The clinic was in an urban academic medical centre where mothers received their obstetric care. Prior to visits, paediatricians received training in counselling parents of newborn infants and breastfeeding techniques/promotion. During visits, paediatricians recorded data on timing of pregnancy, preparation for the infant, involvement of father, social support and maternal medical history. Parents-to-be were counselled on feeding options, advantages of breastfeeding, infant car safety, circumcision and access to paediatric healthcare. Control group (N = 75). Similar management except no prenatal paediatric visits.
Outcomes	Breastfeeding intention before prenatal visit. Breastfeeding initiation at birth. Breastfeeding at 30 days postpartum. Breastfeeding at 60 days postpartum. Mothers who changed their mind in favour of breastfeeding after enrolment. Parent-physician relationship.
Notes	To assess the impact of prenatal paediatrician visits on breastfeeding decisions of low-income mothers

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"The study design was a randomized controlled trial using a random number table with blocks of 10 to assign subjects."
Allocation concealment (selection bias)	Unclear risk	It is unclear whether investigators could have predicted which group a new participant would have been allocated to
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Personnel were not blinded. It is unclear whether participants were blinded to their assigned group
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	"Study outcomes concerning health practices were obtained by maternal interview at enrollment, at the infant's 2-month visit, and by review of the infant's nursery chart. " It is unclear whether outcome assessors were blinded to group allocation. Information obtained from 'Outcomes' section, pg 1070

Serwint 1996 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Breastfeeding initiation data were available for 74/81 participants in the intervention group and 70/75 participants in the control group. Losses were explained adequately, mostly transfer of obstetrician care. Information obtained from Table 1, pg 1071
Selective reporting (reporting bias)	Unclear risk	No trial registration is available.
Other bias	Low risk	"Dyads in the intervention and control group did not differ with regard to maternal age, education, type of medical coverage, week at which prenatal care was initiated, infant gestational age at birth, race, or rate of vaginal delivery." No other obvious source of bias. Data obtained from Table 2, pg 1071

Srinivas 2015

Methods	RCT comparing peer counselling with usual care, with participants stratified based on Iowa Infant Feeding Attitude Scale. Iowa Infant Feeding Attitude Scale administered before birth. Those with a score > 57 were considered to have a positive attitude toward breastfeeding. The Iowa Infant Feeding Attitude Scale score was used to stratify participants according to positive or negative breastfeeding attitude. Study participants were then randomised within these strata in blocks of 4 participants in a 1:1 ratio to intervention (peer counselling) or control (usual care) group. Breastfeeding self-efficacy short form administered within 5 days after birth
Participants	Women ≥ 28 weeks' gestation, ≥ 18 years old, English-speaking, low-income. Women with a diagnosis that was an absolute contraindication to breastfeeding (HIV/AIDS, herpes simplex on the breast, tuberculous lesions of the breast) were excluded
Interventions	Low-intensity peer counselling intervention beginning prenatally. The peer counsellor contacted women between 28 weeks and 1 week prior to delivery, additional contacts were at the mother's request. Peer counsellor also contacted mothers within 5 days of delivery, weekly to 1 month, every 2 weeks to 3 months, and once at 4 months (in person or by phone)
Outcomes	Any and exclusive breastfeeding at 1 and 6 months postpartum. Breastfeeding initiation was considered any breastfeeding attempts after birth. Exclusive breastfeeding was considered duration infant was only breastfeeding or receiving human milk since birth
Notes	

Risk of bias

Srinivas 2015 (*Continued*)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Sequence generation was not described in the paper.
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not described in the paper.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unable to blind participants. Unclear whether investigators were blinded
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome data were collected by the study co-ordinator. Study co-ordinator contacted the control group monthly to assess breastfeeding status so was unblinded to group allocation. "The study coordinator administered the exit interview to both groups either after the mother stopped breastfeeding or after 6 months of breastfeeding, to confirm breastfeeding status as well as perceptions on peer counselling or usual care. " Thus, it seems like the study co-ordinator collected outcome data and was aware of group assignment. Information obtained from 'Recruitment and Study enrolment procedures' section
Incomplete outcome data (attrition bias) All outcomes	Low risk	85% follow-up for the outcome of breastfeeding initiation. Although it's unclear whether there was equal attrition from groups, the final sample sizes are similar so it's likely that it was relatively evenly split. Information obtained from 'Results' section, 1st paragraph
Selective reporting (reporting bias)	Unclear risk	Could not locate trial registration.
Other bias	Low risk	No other obvious sources of bias.

Wambach 2011

Methods	RCT with 3 groups.
Participants	390 adolescent mothers aged 15-18, expecting first child in second trimester of pregnancy, planning to keep the child, can speak and write in English, access to telephone. Multiple pregnancies, preterm births, infants requiring admission to neonatal intensive care and participants with birth complications that prohibited or delayed breastfeeding beyond

	48 hours were excluded. Recruited October 2003-Augst 2006 at 7 prenatal clinics and 4 high schools in the Midwestern USA. Most participants were African-Americans on low incomes. The groups were similar except that more in the intervention group planned to return to school
Interventions	Intervention group (n = 128). Education and counselling based on TPB and developmental theory, and provided by a lactation consultant-peer counsellor team from the second trimester of pregnancy to 4 weeks postpartum. 2 prenatal classes, lasting 90 minutes and 2 hours, used a previously tested breastfeeding education curriculum (Breastfeeding Educated and Supported Teen Club (BEST), Volpe 2000). Peer counsellor prenatal telephone calls provided ongoing decision-making support and information Attention control group (n = 128), to control for non-specific effects of treatment Same amount of education and counselling, focused on healthy pregnancy behaviours and birth preparation, not on breastfeeding Usual care group (n = 134). Received standard care from their respective clinics, which had varying provider types and birth settings
Outcomes	Breastfeeding initiation defined as initiating breastfeeding in the hospital with intention to provide at least half the infant's feedings at the breast or with pumped breast milk, and measured by self-report in hospital Breastfeeding duration defined as the total number of days the mother breastfed or provided breast milk Exclusive breastfeeding.
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"Participants were randomly assigned to one of three study groups: experimental, attention control, or usual care, using a list of random codes." No details are available for how codes were generated
Allocation concealment (selection bias)	Unclear risk	"Patients were randomly assigned to one of three study groups using a list of random codes generated by the study biostatistician."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Non-blinded. Blinding not possible due to nature of the intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Non-blinded.

Wambach 2011 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Reported by group with reasons, in such a way that we could report results by intention-to-treat. Follow-up was: intervention = 77/122 (63%); attention control = 60/115 (52%); usual care = 64/119 (52%) i.e. not high
Selective reporting (reporting bias)	Unclear risk	Study protocol unavailable.
Other bias	High risk	Baseline characteristics were significantly different in the experimental group compared to the other groups regarding plans to continue school and TPB variables

BFHI: Baby-Friendly Hospital Initiative
BMI: body mass index
CBSVs: community-based surveillance volunteers
FSWs: Family Support Workers
GP: general practice
NIMS: Nursing Intervention to Minimise Separation
NMR: neonatal mortality rate
PACU: postanaesthesia care unit
RCT: randomised controlled trial
SBFPC: specialised breastfeeding peer counselling
SPSS: Statistical Package for the Social Sciences
TPB: theory of planned behaviour
WIC/SNPWIC: Supplemental Nutrition Program for Women Infants and Children

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Ahmad 2012	Cross-sectional design; not randomised trial.
Ahmed 2008	Premature infants; intervention after the birth.
Aidam 2005	Not concerned with activity intended to increase breastfeeding initiation rates
Anderson 2005	Not concerned with activity intended to increase breastfeeding initiation rates
Andersson 2013	Trial is a quasi-RCT and does not fit the types of studies for inclusion in this review
Babakazo 2015	Intervention was healthcare staff training to evaluate effect of training on duration of exclusive breastfeeding
Ball 2006	Not concerned with activity intended to increase breastfeeding initiation rates

(*Continued*)

Ball 2011	Not concerned with activity intended to increase breastfeeding initiation rates
Begley 2011	Focus of study is models of care. Powered for breastfeeding initiation outcome, but no details of breastfeeding promotion within the description of the intervention. Participants were allowed to move between intervention groups as deemed necessary
Bica 2014	Intervention took place after birth.
Bishop 1978	No concurrent controls (3 interventions groups, no routine care group). Thus, is not a RCT
Bonuck 2005	Not concerned with activity intended to increase breastfeeding initiation rates
Bonuck 2013	Intervention concerned with breastfeeding duration.
Bottaro 2009	Not concerned with activity intended to increase breastfeeding initiation rates
Byrne 2000	Not concerned with activity intended to increase breastfeeding initiation rates
Carfoot 2001 [pers comm]	Not concerned with activity intended to increase breastfeeding initiation rates
Carfoot 2005	Not concerned with activity intended to increase breastfeeding initiation rates
Cattaneo 2001	Not concerned with activity intended to increase breastfeeding initiation rates
Chapman 1986	Not concerned with activity intended to increase breastfeeding initiation rates
Chapman 2011	Not concerned with activity intended to increase breastfeeding initiation rates
Coutinho 2005	Not concerned with activity intended to increase breastfeeding initiation rates
Di Napoli 2004	Not concerned with activity intended to increase breastfeeding initiation rates
Doherty 2012	Primary outcome was exclusive breastfeeding among women who had already initiated breastfeeding. Not concerned with activity intended to increase breastfeeding initiation rates
Ekstrom 2012	Not concerned with activity intended to increase breastfeeding initiation rates
Feldman 1987	Not concerned with activity intended to increase breastfeeding initiation rates
Forster 2011	Not concerned with activity intended to increase breastfeeding initiation rates
Froozani 1999	Not concerned with activity intended to increase breastfeeding initiation rates
Garcia-Montrone 1996	Non-RCT.
Garmendia 2015	Study protocol only. Primary aims are unrelated to breastfeeding initiation. Thus, not concerned with activity intended to increase breastfeeding initiation rates

(*Continued*)

Girish 2013	Intervention was not support or education (breast crawl) and did not focus on improving or increasing breastfeeding initiation
Gordon 1999	Not concerned with activity intended to increase breastfeeding initiation rates
Graffy 2001 [pers comm]	Not concerned with activity intended to increase breastfeeding initiation rates
Grossman 1988	Contacted authors but unable to acquire sufficient information on method of allocation for this update. Abstract only available
Gurneesh 2009	Not concerned with activity intended to increase breastfeeding initiation rates
Haider 2000	Not concerned with activity intended to increase breastfeeding initiation rates
Hanafi 2014	Quasi-RCT.
Harvey 1996	Not concerned with activity intended to increase breastfeeding initiation rates
Hegedus 2000	Not a RCT (before-after study).
Henderson 2001	Not concerned with activity intended to increase breastfeeding initiation rates
Hirschhorn 2015	Not a RCT (phase II implementation study).
Hives-Wood 2013	Intervention concerned with breastfeeding duration.
Hopkinson 2009	Not concerned with activity intended to increase breastfeeding initiation rates
Howard 2000	Intervention was not for promoting breastfeeding initiation among women
Ijumba 2015	Study population included women with HIV. Thus, did not target the population of interest
Jahan 2014	Intervention was nutrition education, primary outcomes were gestational weight gain and birthweight. Thus, not concerned with activity intended to increase breastfeeding initiation rates
Junior 2007	Very low birthweight babies, not healthy term babies. Thus, did not target the population of interest
Kaplowitz 1983	From information provided, we could not tell whether or not randomisation had taken place. We have written to the authors but have not yet received clarification. Thus, not a RCT
Kastner 2005	Postnatal intervention focussed on measures of the mother-child relationship. Not concerned with activity intended to increase breastfeeding initiation rates
Kistin 1990	Quasi-RCT (women were allocated to the intervention group if they attended clinic on Monday, and to the control group if they attended on Friday)
Kojuri 2009	Not concerned with activity intended to increase breastfeeding initiation rates

(*Continued*)

Kools 2005	Not concerned with activity intended to increase breastfeeding initiation rates
Kramer 2001	This study (PROBIT) was primarily concerned with activity intended to increase the duration, but not the initiation, of breastfeeding
Labarere 2011	Intervention concerned with breastfeeding duration.
Lakin 2015	Intervention took place after birth.
Langer 1996	Not concerned with activity intended to increase breastfeeding initiation rates
Langer 1998	Not concerned with activity intended to increase breastfeeding initiation rates
Lavender 2005	Not concerned with activity intended to increase breastfeeding initiation rates
Loh 1997	Quasi-RCT (intervention was delivered in alternate weeks).
Lucchini 2013	The study is not concerned with activity intended to increase breastfeeding initiation rates. The study aims to encourage exclusive breastfeeding at 2 months; breastfeeding initiation was part of the intervention
MacVicar 1993	Not concerned with activity intended to increase breastfeeding initiation rates
Mahmood 2011	Not concerned with activity intended to increase breastfeeding initiation rates
Martens 2000	Not a RCT (not randomised).
Martens 2001	From information provided, we could not tell whether or not randomisation had taken place. We have written to the authors but have not yet received clarification. Thus, not a RCT
Martin 2013	Only included mothers who had already initiated breastfeeding
Matilla Mont 1999	Not a RCT (before-after study).
Mattar 2007	Contacted authors but unable to acquire sufficient information on method of allocation for this update
Maycock 2013	Intervention was primarily for fathers and not pregnant women. Thus, did not target the population of interest
McEnery 1986	Not a RCT (no randomisation at the point of analysis).
McInnes 2000	Not a RCT (not randomised).
McLachlan 2016	Compared caseload and standard midwifery care on mode of childbirth. Thus, not concerned with activity intended to increase breastfeeding initiation rates

(*Continued*)

McQueen 2011	Postnatal intervention focused on duration and exclusivity of breastfeeding; not concerned with activity intended to increase breastfeeding initiation rates
Moran 2000	Not concerned with activity intended to increase breastfeeding initiation rates
Moreno-Manzanares 1997	Postnatal intervention. At baseline, all the participants had already initiated breastfeeding. Not concerned with activity intended to increase breastfeeding initiation rates
Morhason-Bello 2009	Not concerned with activity intended to increase breastfeeding initiation rates
Morrow 1999	Not concerned with activity intended to increase breastfeeding initiation rates
Nasehi 2012	Early breastfeeding initiation was the intervention, not the outcome. Study aimed to assess the effect of early breastfeeding initiation on exclusive breastfeeding duration
NCT00393640	Focus is on milk production later in lactation. Not concerned with activity intended to increase breastfeeding initiation rates
NCT01916603	The trial was not aimed at promoting breastfeeding initiation
NCT02162498	Participants are all HIV-positive. Thus, did not target the population of interest
Nguyen 2014	Primary purpose was to assess programme impact pathway of Alive & Thrive programme in Vietnam
Nikodem 1998	Not concerned with activity intended to increase breastfeeding initiation rates
Noel-Weiss 2006	Not concerned with activity intended to increase breastfeeding initiation rates
Nor 2012	Report is of a qualitative study conducted within the context of a RCT
Oakley 1990	Not concerned with activity intended to increase breastfeeding initiation rates
Page 1999	Not a RCT (not randomised).
Petrova 2009	Not concerned with activity intended to increase breastfeeding initiation rates
Philipp 2004	Not concerned with activity intended to increase breastfeeding initiation rates
Pisacane 2005	Not concerned with activity intended to increase breastfeeding initiation rates
Pobocik 2000	Quasi-RCT (some school principals would not allow recruitment of control subjects)
Prakhin 2001	Not concerned with activity intended to increase breastfeeding initiation rates
Pugh 2007	Not concerned with activity intended to increase breastfeeding initiation rates

(*Continued*)

Rea 1999	Not concerned with activity intended to increase breastfeeding initiation rates
Redman 1995	Not concerned with activity intended to increase breastfeeding initiation rates
Reifsnider 1996	Not a RCT (not randomised).
Ross 1983	Not concerned with activity intended to increase breastfeeding initiation rates
Rossiter 1994	From information provided, we could not tell whether or not randomisation had taken place. We have written to the authors but have not yet received clarification. Thus, not a RCT
Schafer 1998	Not a RCT (not randomised).
Schlickau 2005	Not concerned with activity intended to increase breastfeeding initiation rates
Schwartz 2015	Intervention took place after birth.
Schy 1996	Not concerned with activity intended to increase breastfeeding initiation rates
Sciacca 1995	Quasi-RCT (randomisation alternate and not concealed).
Scott 1975	Not concerned with activity intended to increase breastfeeding initiation rates
Sellen 2012	Primary purpose was process evaluation of a RCT.
Shaw 1999	Not a RCT (not randomised).
Sisk 2004	Did not target the population of interest.
Spinelli 2013	Women enrolled in a depression treatment programme.
Susin 2008	Not concerned with activity intended to increase breastfeeding initiation rates
Talukder 2016	Intervention was training for traditional birth attendants.
Toma 2001	Not a RCT (not randomised).
Turan 2001	Not concerned with activity intended to increase breastfeeding initiation rates
Turnbull 1996	Not concerned with activity intended to increase breastfeeding initiation rates
Tylleskar 2011	Not concerned with activity intended to increase breastfeeding initiation rates
Vaidya 2005	Not concerned with activity intended to increase breastfeeding initiation rates
van den Bosch 1990	Not concerned with activity intended to increase breastfeeding initiation rates

(*Continued*)

Vianna 2011	Participants are premature infants in Special Care Baby Units, not healthy term babies
Volpe 2000	Quasi-RCT (randomisation not concealed, comparison groups not concurrent)
Waldenstrom 1994	Not concerned with activity intended to increase breastfeeding initiation rates
Westphal 1995	This was an evaluation of staff training around the 10 steps of the BFHI and did not specifically focus on breastfeeding initiation
Wiles 1984	Not concerned with activity intended to increase breastfeeding initiation rates
Winterburn 2003	Contacted authors but unable to acquire sufficient information on method of allocation for this update
Winters 1973	Focus is time to initiation of breastfeeding. Not concerned with activity intended to increase breastfeeding initiation rates and does not report them
Wolfberg 2004	Intervention was primarily for fathers and not pregnant women
Woolridge 1985	Intervention is timing of initiation of breastfeeding. Outcome is milk transfer. Not concerned with activity intended to increase breastfeeding initiation rates and does not report them
Yotebieng 2015	Intervention was for healthcare staff training on BFHI Steps 1 through 10
Zimmerman 1999	Not a RCT (not randomised).

BFHI: Baby Friendly Hospital Initiative
PROBIT: Promotion of breastfeeding intervention trial
RCT: randomised controlled trial

Characteristics of studies awaiting assessment *[ordered by study ID]*

Bakhshi 2015

Methods	Randomised clinical trial study.
Participants	80 primigravida women attending Mashahd Omlbanin Hospital randomly allocated in to 2 groups (n = 40 per group)
Interventions	The intervention group and the control group received supportive care and routine care, respectively
Outcomes	Onset of lactogenesis II.
Notes	Language is in Persian, need translation.

Samieizadeh 2011

Methods	Unclear.
Participants	210 primiparous mothers.
Interventions	Psychosocial support during labour, delivery and the immediate postpartum period provided by a female companion of choice
Outcomes	Duration of labor, time of delivery, Apgar scores, breastfeeding intent and early breastfeeding initiation 1-hour after birth
Notes	Language is in Persian, need translation.

Characteristics of ongoing studies *[ordered by study ID]*

ISRCTN23019866

Trial name or title	Building Blocks - a trial of home visits for first time mothers
Methods	Individually-randomised controlled trial.
Participants	Young first time mothers (19 yrs old or under).
Interventions	Participants will be randomised to either entry into the FNP arm or to the control arm (universal services), and will be followed up until 2 years after the birth of the child. The whole trial will last 52 months. Interviews (either face-to-face or by telephone) for both arms of the trial will be at baseline, 34-36 weeks' gestation and 6, 12, 18, and 24 months after birth. If participants are selected to join the group that receives the FNP, they will receive visits from a specially trained 'Family Nurse'. The Family Nurse would normally go to the participants' home, but can be elsewhere. The Family Nurse will visit the participant every week for the first month after they join the study, and then every other week until the baby is born. The Family Nurse will then visit the participant weekly until the baby is 6 weeks old and then once every 2 weeks until the child is 20 months old. The last 4 visits are monthly until the child is 2 years old
Outcomes	1. Changes in prenatal tobacco use (maternal measure), measured at baseline and 34-36 weeks' gestation interviews 2. Birthweight (child measure), measured at birth (collected afterwards) 3. Emergency attendances/admissions within 2 years of birth, measured at all time points 4. Proportion of women with a second pregnancy within 2 years of first birth, measured at all time points 5. Intention to breastfeed 6. Prenatal attachment 7. Injuries and ingestions 8. Breast feeding (initiation and duration) 9. Language development 10. Education 11. Employment 12. Income/benefits 13. Home (tenure) 14. Health status

ISRCTN23019866 (*Continued*)

	15. Self-efficacy 16. Social support 17. Paternal involvement
Starting date	24/03/2009.
Contact information	Dr Mike Robling Associate Director South East Wales Trials Unit Department of Primary Care and Public Health 7th Floor Neuadd Meirionnydd Cardiff University Heath Park Cardiff CF14 4YS United Kingdom
Notes	ISRCTN23019866

Kimani-Murage 2013

Trial name or title	MIYCN Intervention Study.
Methods	Women will be recruited into the study and randomised to the intervention or control group. Women in the intervention group will receive regular, home-based counselling on maternal, infant, and young child nutrition. Mother-infant dyads will be followed up until the child is 1 year old. Mothers will be regularly assessed on knowledge, attitudes, and practices regarding maternal, infant, and young child nutrition
Participants	780 pregnant women, and the children subsequently born to them, from 2 slums in Nairobi
Interventions	In the intervention arm, CHWs will visit pregnant woman roughly once every month up to 34 weeks' gestation, after 34 weeks' visits will occur weekly until delivery. After delivery, CHWs will visit the mother weekly in the first 1 month. CHWs will counsel women during pregnancy and counselling will continue until 1 year after delivery. Women will be counselled on maternal nutrition, early initiation of breastfeeding, breastfeeding positions and attachment, exclusive breastfeeding, frequency and duration of breastfeeding, human milk expression, and the storage and handling of human milk
Outcomes	Primary outcome is exclusive breastfeeding for 6 months. Early breastfeeding initiation is listed as a secondary outcome in Table 2. Other secondary outcomes include breastfeeding and complementary feeding knowledge and attitudes, the duration of any breastfeeding, complementary feeding practices, nutritional status, morbidity from diarrhoea, and cost-effectiveness
Starting date	September 2012.
Contact information	Dr Kimani-Murage: ekimani@aphrc.org
Notes	

NCT02084680

Trial name or title	Intervention trial to measure the effect of individual prenatal information combined with mobile phones
Methods	This is a pragmatic community randomised trial. 8 health centres will be randomised to an intervention arm and 8 will be randomised to a control arm. VHTs were trained for 5 consecutive days on intervention delivery
Participants	All women attending their first antenatal consultation prior to 28 weeks' gestation were eligible to participate, regardless of parity. There were no exclusion criteria
Interventions	The intervention arm will receive VHTs equipped with mobile phones who will make scheduled home visits to pregnant women. VHTs will discuss birth preparation, signs of problems during pregnancy, obtaining items necessary for delivery, and newborn care practices
Outcomes	Primary outcomes include hygienic cord care, thermal care, early initiation of breastfeeding (within 1-hour of birth), and avoidance of pre-lacteal feeds
Starting date	June 2013.
Contact information	Dr Mangwi Ayiasi: rmangwi@musph.ac.ug
Notes	

Williams 2015

Trial name or title	WASH Benefits.
Methods	WASH Benefits is a 7-armed cluster-randomised trial of water, sanitation, hygiene, and nutrition interventions. This community-based cluster-randomised controlled trial included an infant and young child feeding (IYCF) behaviour change component
Participants	Women in their 2nd or 3rd trimester of pregnancy.
Interventions	Nutrition behaviour change communication on breastfeeding and maternal postpartum nutrition practices
Outcomes	Early initiation of breastfeeding (less than or equal to 1-hour after birth)
Starting date	
Contact information	cpstewart@ucdavis.edu
Notes	

CHW: community health workers
FNP: family nurse programme
VHT: village health teams

DATA AND ANALYSES

Comparison 1. Healthcare professional-led breastfeeding education and support versus standard care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Initiation of breastfeeding	5		Risk Ratio (Random, 95% CI)	1.43 [1.07, 1.92]

Comparison 2. Non-healthcare professional-led breastfeeding education and support versus standard care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Initiation of breastfeeding	8		Risk Ratio (Random, 95% CI)	1.22 [1.06, 1.40]
1.1 Low-income or minority-ethnic population	6		Risk Ratio (Random, 95% CI)	1.21 [1.04, 1.40]
1.2 General population	2		Risk Ratio (Random, 95% CI)	1.30 [0.90, 1.88]
2 Early initiation of breastfeeding	3		Risk Ratio (Random, 95% CI)	1.70 [0.98, 2.95]

Comparison 3. Healthcare professional-led breastfeeding education with non-healthcare professional support versus standard care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Initiation of breastfeeding	2	895	Risk Ratio (M-H, Random, 95% CI)	1.06 [0.88, 1.27]

Comparison 4. Healthcare professional-led breastfeeding education with peer support versus attention control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Initiation of breastfeeding	1	237	Risk Ratio (M-H, Fixed, 95% CI)	1.21 [0.97, 1.51]

Comparison 5. Breastfeeding education using multimedia versus routine care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Initiation of breastfeeding	2	497	Risk Ratio (M-H, Random, 95% CI)	1.16 [0.63, 2.14]

Comparison 6. Early mother-infant contact versus standard care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Initiation of breastfeeding	2	309	Risk Ratio (M-H, Fixed, 95% CI)	1.08 [0.97, 1.20]

Comparison 7. Community-based breastfeeding groups versus no breastfeeding groups

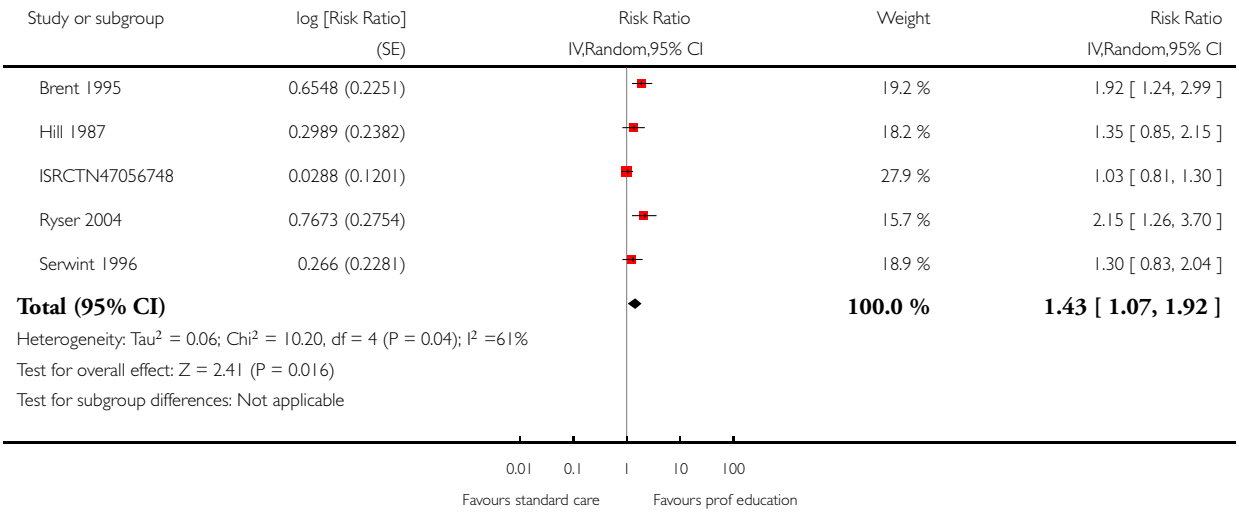
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Breastfeeding rate at birth	1	18603	Mean Difference (Random, 95% CI)	-0.01 [-0.05, 0.03]

Analysis 1.1. Comparison 1 Healthcare professional-led breastfeeding education and support versus standard care, Outcome 1 Initiation of breastfeeding.

Review: Interventions for promoting the initiation of breastfeeding

Comparison: 1 Healthcare professional-led breastfeeding education and support versus standard care

Outcome: 1 Initiation of breastfeeding

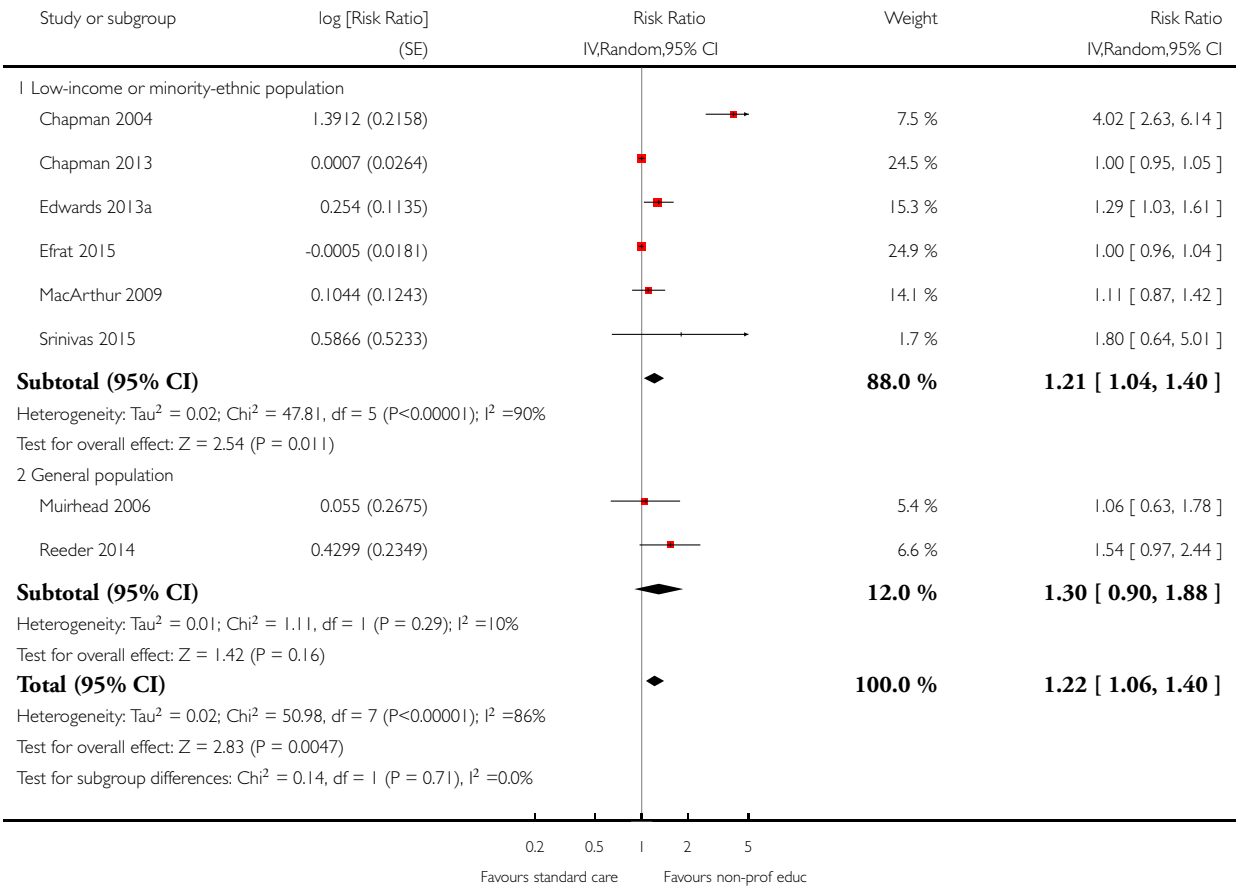


Analysis 2.1. Comparison 2 Non-healthcare professional-led breastfeeding education and support versus standard care, Outcome 1 Initiation of breastfeeding.

Review: Interventions for promoting the initiation of breastfeeding

Comparison: 2 Non-healthcare professional-led breastfeeding education and support versus standard care

Outcome: 1 Initiation of breastfeeding

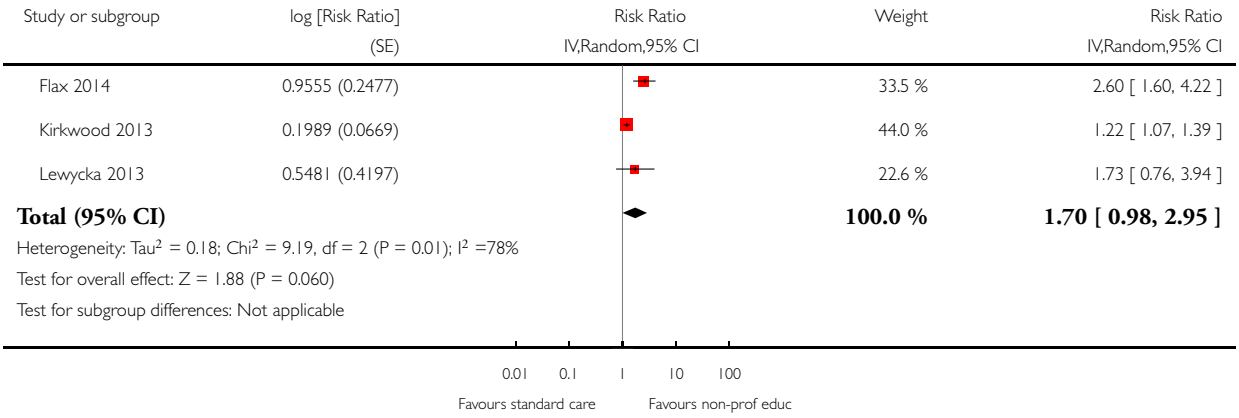


Analysis 2.2. Comparison 2 Non-healthcare professional-led breastfeeding education and support versus standard care, Outcome 2 Early initiation of breastfeeding.

Review: Interventions for promoting the initiation of breastfeeding

Comparison: 2 Non-healthcare professional-led breastfeeding education and support versus standard care

Outcome: 2 Early initiation of breastfeeding



Analysis 3.1. Comparison 3 Healthcare professional-led breastfeeding education with non-healthcare professional support versus standard care, Outcome 1 Initiation of breastfeeding.

Review: Interventions for promoting the initiation of breastfeeding

Comparison: 3 Healthcare professional-led breastfeeding education with non-healthcare professional support versus standard care

Outcome: 1 Initiation of breastfeeding

Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Forster 2004	296/327	297/327		65.0 %	1.00 [0.95, 1.05]
Wambach 2011	77/122	64/119		35.0 %	1.17 [0.95, 1.45]
Total (95% CI)	**449**	**446**		**100.0 %**	**1.06 [0.88, 1.27]**

Total events: 373 (Experimental), 361 (Control)

Heterogeneity: $Tau^2 = 0.01$; $Chi^2 = 3.01$, df = 1 (P = 0.08); $I^2 = 67\%$

Test for overall effect: Z = 0.58 (P = 0.56)

Test for subgroup differences: Not applicable

Analysis 4.1. Comparison 4 Healthcare professional-led breastfeeding education with peer support versus attention control, Outcome 1 Initiation of breastfeeding.

Review: Interventions for promoting the initiation of breastfeeding

Comparison: 4 Healthcare professional-led breastfeeding education with peer support versus attention control

Outcome: 1 Initiation of breastfeeding

Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Wambach 2011	77/122	60/115		100.0 %	1.21 [0.97, 1.51]
Total (95% CI)	**122**	**115**		**100.0 %**	**1.21 [0.97, 1.51]**

Total events: 77 (Experimental), 60 (Control)

Heterogeneity: not applicable

Test for overall effect: Z = 1.69 (P = 0.092)

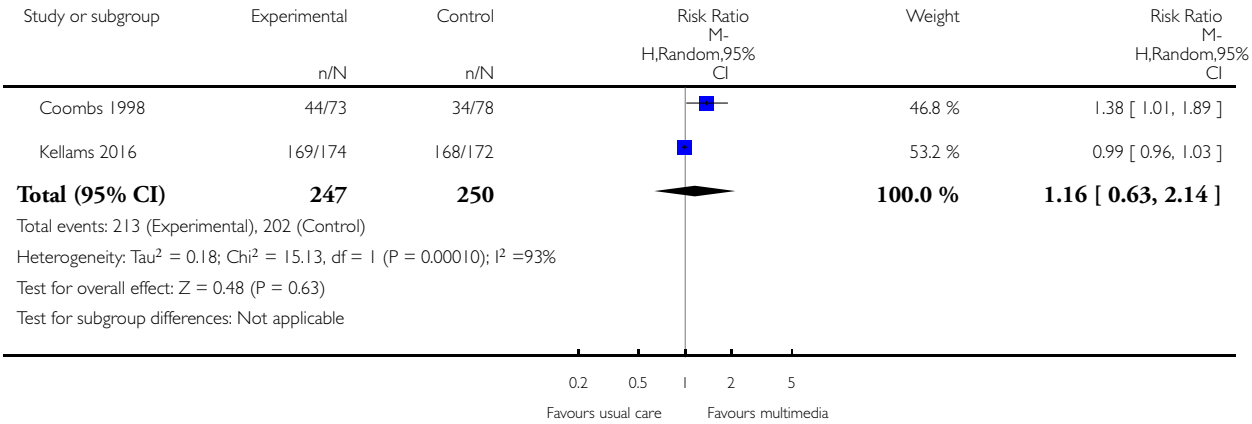
Test for subgroup differences: Not applicable

Analysis 5.1. Comparison 5 Breastfeeding education using multimedia versus routine care, Outcome 1 Initiation of breastfeeding.

Review: Interventions for promoting the initiation of breastfeeding

Comparison: 5 Breastfeeding education using multimedia versus routine care

Outcome: 1 Initiation of breastfeeding



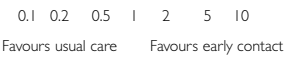
Analysis 6.1. Comparison 6 Early mother-infant contact versus standard care, Outcome 1 Initiation of breastfeeding.

Review: Interventions for promoting the initiation of breastfeeding

Comparison: 6 Early mother-infant contact versus standard care

Outcome: 1 Initiation of breastfeeding

Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Lindenberg 1990	117/136	101/123		87.6 %	1.05 [0.94, 1.17]
Nolan 2009	20/25	15/25		12.4 %	1.33 [0.92, 1.94]
Total (95% CI)	**161**	**148**		**100.0 %**	**1.08 [0.97, 1.20]**
Total events: 137 (Experimental), 116 (Control)					
Heterogeneity: Chi^2 = 1.55, df = 1 (P = 0.21); I^2 =36%					
Test for overall effect: Z = 1.48 (P = 0.14)					
Test for subgroup differences: Not applicable					



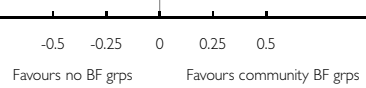
Analysis 7.1. Comparison 7 Community-based breastfeeding groups versus no breastfeeding groups, Outcome 1 Breastfeeding rate at birth.

Review: Interventions for promoting the initiation of breastfeeding

Comparison: 7 Community-based breastfeeding groups versus no breastfeeding groups

Outcome: 1 Breastfeeding rate at birth

Study or subgroup	Community-based BF grps N	No BF grps N	Mean Difference (SE)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
Hoddinott 2009 (1)	9635	8968	-0.009 (0.0184)		100.0 %	-0.01 [-0.05, 0.03]
Total (95% CI)	**9635**	**8968**			**100.0 %**	**-0.01 [-0.05, 0.03]**
Heterogeneity: not applicable						
Test for overall effect: Z = 0.49 (P = 0.62)						
Test for subgroup differences: Not applicable						



(1) Difference in the proportion of women practising any breastfeeding just after birth - adjusted for pre-intervention breastfeeding rates and clustering

APPENDICES

Appendix 1. Note 1

Unless otherwise stated, the sources of international breastfeeding data are the WHO Global Strategy for Infant and Young Child Feeding (WHO 2003), or the WHO Global Databank on Breast-Feeding (WHO Data Bank 1996). The Databank is not comprehensive at this time and is dependent on data collected by individual countries using a variety of methods or indicators, or both.

Appendix 2. Note 2

Figures presented are not standardised for mother's age and age at which she completed full-time education, factors strongly associated with the incidence of breastfeeding. Standardised figures were not available for individual countries. Available data for changes in breastfeeding rates for England and Wales between 2000 and 2005, when standardised for mother's age and education, report a real increase in breastfeeding rates which was not simply due to changes in the sample composition (Bolling 2007).

WHAT'S NEW

Last assessed as up-to-date: 29 February 2016.

Date	Event	Description
28 November 2016	Amended	Corrected typographical errors and setting in 'Summary of findings' table

HISTORY

Protocol first published: Issue 3, 1999

Review first published: Issue 2, 2005

Date	Event	Description
29 February 2016	New citation required but conclusions have not changed	Conclusions not changed.
29 February 2016	New search has been performed	Search updated. Methods updated. In this update, we excluded two trials (Howard 2000; Lucchini 2013), one of these was included in the pre-

(*Continued*)

		vious review (Howard 2000). We added 22 new trials in this update (Caulfield 1998; Chapman 2004; Chapman 2013; Edwards 2013a; Edwards 2013b; Efrat 2015; Flax 2014; Forster 2004; Hoddinott 2009; Ickovics 2007; Ickovics 2016; Kellams 2016; Kirkwood 2013; Lewycka 2013; MacArthur 2009; Muirhead 2006; Nolan 2009; Reeder 2014; Sandy 2009; ISRCTN47056748; Srinivas 2015; Wambach 2011). This update (2016) now includes 28 trials and excludes 125 trials
15 January 2008	Amended	Converted to new review format.
4 December 2007	New search has been performed	Search updated and 25 new trials identified. We included five new trials, (Caulfield 1998a; Chapman 2004; Forster 2004a; Ryser 2004; Wolfberg 2004a) and excluded 21 new trials (Aidam 2005; Anderson 2005; Ball 2006; Bonuck 2005; Carfoot 2005; NCT00393640; Coutinho 2005; Di Napoli 2004; Garcia-Montrone 1996; Grossman 1988; Kools 2005; Lavender 2005; Mattar 2007; Muirhead 2006a; Noel-Weiss 2006; Philipp 2004; Pisacane 2005; Schlickau 2005; Sisk 2004; Vaidya 2005; Winterburn 2003).
30 May 2006	Amended	Corrected data error in Graph 01.01 for Brent 1995. No change to conclusions. Search updated. Twenty-four new trial reports added to 'Awaiting assessment' for next update, which is currently being prepared.

CONTRIBUTIONS OF AUTHORS

The 2016 update (which involves new authors):

- Olukunmi Balogun: independent screening, data extraction, quality appraisal, analysis and synthesis of findings, edited and updated results, and revised the manuscript.

- Elizabeth J O'Sullivan: data extraction, quality appraisal, analysis and synthesis of findings, updated results, and revised the manuscript.

- Alison McFadden: edited results and discussion, and revised the manuscript.

- Erika Ota: data extraction, quality appraisal, analysis and synthesis of findings, and 'Summary of findings' tables.

- Anna Gavine: edited results and discussion, and revised the manuscript.

- Christine Dieterich Garner: independent prescreening, data extraction, and quality appraisal.

- Mary Renfrew (contact author): revised the manuscript.

- Steve MacGillivray: applied the study selection criteria, edited results and discussion, and revised the manuscript.

All the authors read and approved the final version to be published.

DECLARATIONS OF INTEREST

Olukunmi O Balogun: none known.

Elizabeth J O'Sullivan: none known.

Alison McFadden: none known.

Erika Ota: none known.

Anna Gavine: none known.

Christine D Garner: none known.

Mary J Renfrew: none known.

Stephen MacGillivray: none known.

SOURCES OF SUPPORT

Internal sources

- Mother and Infant Research Unit, University of Leeds, UK.

External sources

- Canadian Cochrane Child Health Field Bursary Award, Canada.
- York Centre for Reviews and Dissemination, UK.
- Evidence and Programme Guidance Unit, Department of Nutrition for Health and Development, World Health Organization, Switzerland.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Methods updated to current standard text of Cochrane Pregnancy and Childbirth.

We have edited the main outcomes from 'Initiation and duration of any and exclusive breastfeeding' to:

1. initiation of breastfeeding;
2. early initiation of breastfeeding (within one hour after birth).

We have assessed the quality of the body of evidence using the GRADE approach.

We have redefined our planned subgroup analysis to be based on low-income (or minority-ethnic) population versus the general population.

In protocol but not review - Types of participants: In order to examine intermediate/process outcomes, other participants exposed to such interventions, for example partners, health professionals and employers will be considered.

In protocol but not review - Types of outcomes: Process outcomes (health literacy, public policy, social influence).

INDEX TERMS

Medical Subject Headings (MeSH)

Breast Feeding [*psychology; statistics & numerical data]; Counseling [methods]; Health Education [*methods]; Peer Group; Randomized Controlled Trials as Topic

MeSH check words

Female; Humans